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Bayer HealthCare

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By Hand Delivery

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Re: CMS-1270-P: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Medicare Prescription Drug Benefit

Dear Administrator McClellan:

Bayer HealthCare ("Bayer") submits these comments to the Proposed Rule titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (CMS-1270-P). We appreciate the Centers for Medicare and Medicaid Services' ("CMS") careful consideration of these comments and other suggestions from the supplier, physician, and patient communities. We commend CMS for its thoughtful implementation of the competitive bidding program and look forward to working together to develop an effective program that reduces costs for the Medicare program without compromising access to the quality diabetes care management products currently available to beneficiaries.

We are impressed by CMS' energetic efforts to plan the implementation of the competitive bidding program as Congress intended. We appreciate CMS requesting comments on these proposals and we would like to take the opportunity to offer specific suggestions with respect to the provision of durable medical equipment ("DME") products and supplies to beneficiaries with diabetes and more general comments to facilitate the overall implementation of the competitive bidding program. Due to the unique issues that are associated with the clinical

management of diabetes, we believe that it is critical that CMS incorporate the following thoughts and suggestions into the final rule.

Summary of Bayer Recommendations:

- CMS should exclude blood glucose monitors and other diabetes-related supplies in the initial phase of the competitive bidding program to ensure a smooth transition of these products into the new supply system since uninterrupted access to supplies is critical for management of diabetes and the prevention of complications associated with the disease.
- CMS should recognize the longstanding policy of the United States government to give small businesses an opportunity to compete for government contracts by declining to waive provisions of the Federal Acquisition Regulation that protect the interests of small businesses. In addition CMS must establish a means of providing assistance and information to beneficiaries and evaluating their satisfaction during and after the implementation process in order to maintain access to and quality of DME items supplied through competitive bidding.
- CMS should further ensure the participation of smaller suppliers by strengthening its networking provisions to give small businesses a meaningful opportunity to participate in the bidding process, which will benefit the process as a whole by expanding the pool of available bidders.
- CMS should continue to respect the clinical expertise of physicians and the individual needs of beneficiaries by ensuring that successful bid suppliers provide the brand and model of equipment and supplies that have been prescribed by the treating physician just as CMS required of its Medicare Part D plan providers.
- CMS should abandon the provision of rebates to beneficiaries by suppliers who bid below the single payment price due to the unfair advantage that these suppliers will have over other suppliers who are unable to provide such rebates and the serious fraud and abuse risks that would result from the implementation of this provision.
- CMS should not import bid prices into non-bid areas because of the lack of an economically sound method for transferring prices to a fundamentally different economic system.
- CMS should reconsider its requirement that non-competitive bidding suppliers receive the payment amount set by the beneficiaries' home competitive bidding area ("CBA") when the suppliers are providing supplies to beneficiaries who are traveling to other CBAs or to non-bid areas, in order to minimize the risk of refusal of local suppliers to provide products at rates that are lower than what they would normally receive for an item.

- CMS should more explicitly articulate the fundamental technical aspects of the bidding process and discuss how it will evaluate the sustainability of bids. CMS should seriously consider basing the pivotal bid of each competitive bid area on 125 percent of projected demand to avoid shortfall in supplies.
- CMS should reconsider use of a pivotal bid to establish the payment amount for an item because this methodology carries an inherent risk of failing to secure contracts with an adequate number of suppliers.
- CMS should reconsider its desire to force all beneficiaries to participate in a nationwide mail order system given the important role of local retail pharmacists in disease management and both the preference of, and convenience for, many beneficiaries who would chose to continue obtaining their diabetes-related supplies, which are widely available at the local retail level, from their neighborhood pharmacy. We recommend that CMS adopt the same geographic access provisions as CMS applied under the Medicare Part D program.
- CMS should use the CPI-health index to make inflation increase calculations more accurate, and CMS should explain how this provision operates for items that are currently under a price freeze in the fee schedule.
- CMS should modify the change in ownership provision by removing the sixty-day prior notification requirement and allowing successor entities to continue supplying beneficiaries in a CBA as the winning contract supplier as long as they meet the general requirements for contract suppliers.
- CMS should quickly establish thorough quality standards to assist suppliers in submitting the most accurate bid possible and CMS should set a separate comment period on its quality standards to more fully examine the impact and interplay of the quality standards with the competitive bidding program.
- CMS should exclude new DMEPOS items from the competitive bidding process to allow for the integration and acceptance of the new technology into the medical community before adding it to the list of bid items and applying the proposed gap-filling methodology. CMS should hold a second comment period to address the complexities related to the gap-filling process.
- CMS must establish an emergency provision that will allow beneficiaries to obtain needed DMEPOS from their old suppliers during the transition to the new supply system to avoid short term access issues.

I. Serious Health Consequences of Diabetes and Need to Provide Quality Diabetes-Related Supplies and Services

Bayer is a major manufacturer of blood glucose monitoring equipment and supplies that has been providing high quality diabetes-related products to generations of beneficiaries. Bayer's commitment to supplying patients with diabetes with the necessary blood glucose monitoring equipment and supplies has played a role in fighting the growing epidemic of diabetes. This is because, unlike most durable medical equipment, blood glucose monitors are diagnostic as well as therapeutic. Blood glucose monitors enable beneficiaries with diabetes to accurately self-diagnose their blood glucose levels, which in turn allows them to achieve desired therapeutic results by altering their diet or medication dosages. Medicare beneficiaries depend on wide access to high quality diabetes-related supplies and services to ensure their long-term welfare.

Diabetes, both Type 1 and Type 2, is characterized by elevated levels of sugar in the blood. Type 1 diabetes, a malfunction of the immune system, affects approximately a million people in the United States.[1] In Type 1, the immune system destroys the cells in the pancreas that make insulin.[2] In Type 2, the body's cells are not sufficiently receptive to insulin, or the pancreas makes too little of it, or both.[3] Approximately 95 percent of all cases are Type 2 diabetes.[4] This is of concern because Type 2 diabetes afflicts roughly 20 million Americans and is the nation's fastest growing health problem.[5]

Educators and public health experts are alarmed by the explosive growth of diabetes as it continues to be the only major disease with a death rate that is still rising.[6] The deadly disease now contributes to the deaths of 225,000 Americans each year.[7] The American Public Health Association has stated that diabetes "is clearly one of the most important threats facing us."[8] The American Diabetes Association has noted that the disease could actually lower the average life expectancy of Americans for the first time in more than a century.[9]

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[1] *See* Richard Perez-Pena, *Beyond 'I'm a Diabetic,' Little Common Ground*, N.Y. TIMES, May 17, 2006.
[2] *See* N.R. Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis*, N.Y. TIMES, Jan. 9, 2006.
[3] *See id.*
[4] *See id.*
[5] *See* Perez-Pena, *Beyond 'I'm a Diabetic,' Little Common Ground.*
[6] *See* Ian Urbina, *Rising Diabetes Threat Meets a Falling Budget*, N.Y. TIMES, May 16, 2006.
[7] *See id.*
[8] *See* Urbina, *Rising Diabetes.*
[9] *See* N.R. Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis*, N.Y. TIMES, Jan. 9, 2006.

Diabetes is the leading cause of kidney failure, blindness and non-traumatic amputation.[10] Just in the city of New York alone, there are roughly 2,000 largely avoidable diabetes-related amputations every year.[11] Patients with diabetes are two to four times more likely than others to develop heart disease or have a stroke, and three times more likely to die of complications from flu or pneumonia, according to the Centers for Disease Control ("CDC").[12] According to the CDC, during a twenty-four hour period, 4,100 people are diagnosed with diabetes; 230 amputations occur in people with diabetes; 120 people enter end-stage kidney disease programs; and 55 people go blind.[13]

Diabetes is destructive not only to an individual's body but also poses serious economic and social consequences. The American Diabetes Association estimates that the disease costs the U.S. economy about $132 billion per year for treatment and lost productivity at work.[14] Health officials fear that within a generation or so, a huge wave of new cases could overwhelm the public health system and engulf growing numbers of the population where cities will be crippled by the disease's damage.[15]

Although diabetes is a chronic disease, careful and consistent blood glucose monitoring can reduce negative health outcomes. Increased blood glucose levels affect every major organ in the body, and failure to adequately control blood glucose levels can lead to kidney failure, blindness, heart attacks, strokes, loss of feeling in the hands and feet, and decreased blood flow in the legs.[16] Loss of sensation and decreased blood flow in the legs can lead to ulcers, gangrene, and ultimately amputation of the lower extremities. These serious complications of diabetes can be minimized or at least delayed when the disease is controlled. In fact, diabetes is recognized as one chronic disease for which quality improvement efforts can make great strides.[17]

The most vital part of controlling diabetes is accurate and consistent daily self-monitoring of blood glucose levels. Blood glucose monitors allow beneficiaries with diabetes to check their blood glucose level to ensure that it is neither too high or too low. This daily diagnostic testing is the only way that

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[10] *See id.*
[11] *See* Ian Urbina, *In the Treatment of Diabetes, Success Often Does Not Pay*, N.Y. TIMES, Jan. 11, 2006.
[12] *See* Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis.*
[13] *See id.*
[14] *See* Urbina, *supra* note 11.
[15] *See* Kleinfield, *supra* note 12.
[16] *See* CDC, *Prevent and Control Diabetes*, at 4, *available at* http://www.cdc.gov/diabetes/pubs/prevent.htm (last visited Jun. 15, 2006).
[17] *See* HHS, Agency for Healthcare Research and Quality (AHRQ), *Diabetes Care Quality Improvement: A Resource Guide for State Action*, No. 04-0072, at 18 (Sept. 2004), *available at* http://www.ahrq.gov/qual/diabqguide.pdf (last visited Jun. 14, 2006).

beneficiaries have to maintain their blood glucose level as close as possible to the normal range, which is the key to controlling their disease and minimizing the risk of complications. The first step for every beneficiary with diabetes in managing their disease and avoiding these potential complications is to obtain the correct glucose monitor. Selecting the right monitor is a critical and personal decision that a patient and doctor must make together based on the patient's individual needs. Not all monitors are the same. For example, some have features that allow older patients with arthritis to maneuver and handle the monitor more easily. Some monitors have larger screens that can be read by patients with visual impairments.

Tailoring the blood glucose monitor to the needs of patients so that patients can consistently and accurately monitor their diabetes is essential. Once a beneficiary is using a device that is suited to his or her needs, it is important that the beneficiary continues to have access to the strips and other supplies that are unique to the monitoring system that he or she is using. If the blood glucose monitoring system does not match the beneficiary's needs, the beneficiary may not be motivated to continue self-testing. We urge CMS to remember, when determining how best to implement the competitive bidding process for durable medical equipment, the unique issues associated with beneficiaries with diabetes and the high risk of harm that may result if these beneficiaries do not have access to appropriate, high-quality diabetes monitoring supplies to help keep in check what is one of the most significant public health concerns.

II. Competitive Bidding Areas (Proposed § 414.410)

Given the lack of statutory mandate to include diabetes care items in the 2007 competitive bidding program and the lack of inclusion of diabetes care items through the demonstration projects, exclusion of the diabetes-related supplies in the 2007 phase of the competitive bidding program is warranted. We encourage CMS to implement competitive bidding for diabetes-related supplies in a controlled manner within a limited area.

If CMS decides to include diabetes-related supplies in the competitive bidding program, we request that CMS exercise its discretion to exclude diabetes-related supplies from the competitive bidding program in this initial phase of the implementation. The Medicare Modernization Act ("MMA") clearly does not require CMS to include diabetes care supplies within the ten Metropolitan Statistical Areas ("MSAs") selected for competitive bidding in 2007. Since CMS has not yet identified the specific products that will be included in the 2007 phase, it can easily and should reserve the diabetes-related items for a later phase, consistent with the discretionary authority granted by the MMA.

Since the San Antonio and Polk County demonstration projects did not include diabetes care items, CMS simply has insufficient history to proceed with

these products in the ten largest MSAs in 2007. Without the experience afforded by a demonstration project, the potential for beneficiary harm exists due to potential barriers to access and increased risk of beneficiary non-compliance. The competitive bidding report issued by the Government Accountability Office ("GAO") noted CMS' decision not to include glucose monitors and supplies in the San Antonio and Polk County locations "because beneficiaries must frequently use brand-name supplies with their monitors."[18] CMS was rightly concerned that there are complicated operational issues for implementing competitive bidding for diabetes-related supplies due to certain beneficiaries' need for specific brands of glucose test strips.[19] Unfortunately, CMS still does not have any information on how access to diabetes-related supplies will be affected by the competitive bidding program. Furthermore, CMS has limited knowledge of how the quality standards will affect the availability of a wide pool of suppliers who are able to provide diabetes-related supplies or their willingness to participate in the program itself. The additional information available after a demonstration project for diabetes-related supplies or a limited implementation phase can be invaluable in anticipating unforeseen problems with beneficiary access and assisting CMS in maximizing its cost savings.

Despite CMS' extraordinary effort and careful consideration in establishing the Medicare Part D program, there were unexpected operational issues that arose during the course of implementation. That experience should impart CMS with a sense of caution about proceeding with sweeping programmatic changes without significant data on the impact of those changes.

If and when CMS decides to include diabetes-related supplies in the competitive bidding program, Bayer recommends that CMS implement competitive bidding for blood glucose monitoring items in a controlled manner initially within a limited area to test access, quality and cost savings. A thoughtfully designed, limited implementation plan is entirely consistent with the MMA. Careful control and analysis of the data derived from such an approach will support CMS in implementing a successful competitive bidding program for diabetes care management supplies. More importantly, controlled implementation will also provide greater protection to beneficiaries who depend on access to quality diabetes care management products. The long-term health and wellness of beneficiaries with diabetes cannot be placed in jeopardy by an inadequate program design or flawed implementation.

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[18] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 10.
[19] *See id.*

III. Implementation Contractor (Proposed § 414.406) - Federal Acquisition Regulation Waiver and Beneficiary Satisfaction

CMS intends to use one or more Competitive Bidding Implementation Contractors ("CBICs") to help with design, oversight, access and quality management, bid evaluation, and beneficiary outreach and education for the competitive bidding program. We have two concerns regarding the Proposed Rule's description of CMS' use of CBICs. We believe that waiver of all requirements of the Federal Acquisition Regulation ("FAR")[20] will decrease the opportunity for small businesses to compete with larger firms to become a contract supplier. We believe that CMS must provide, through the CBICs, easily accessible help for beneficiaries who may experience difficulties integrating into the new system. In addition, CMS must provide a means for beneficiaries to rate their experience with suppliers in order to maintain high quality service.

A. Federal Acquisition Regulation Waiver

Bayer opposes the waiver of the FAR to the extent that small business interests are not adequately protected by such waiver. Such a waiver would both undermine the Small Business Act and the effectiveness of competitive bidding by decreasing the pool of suppliers and, ultimately, reducing the potential for cost savings.

It is the policy of the United States to give small businesses the opportunity to participate in federal procurements, both as prime contractors and as subcontractors, pursuant to the Small Business Act, Pub. L. 85-536, enacted in 1958, as well as the FAR. In addition, it is the policy of the federal government to encourage the participation of socially and economically disadvantaged businesses in federal procurements.

The Small Business Act best explains the basis for a longstanding policy favoring significant participation of small businesses in federal procurements. In relevant part, it states:

> The essence of the American economic system of private enterprise is free competition. Only through full and free competition can free markets, free entry into business, and opportunities for the expression and growth of personal initiative and individual judgment be assured. The preservation and expansion of such competition is basic not only to the economic well-being but to the security of this nation. Such security and well-being cannot be realized unless the actual and potential capacity of small business is encouraged and developed. It is

[20] *See* 48 C.F.R. ch. 1.

> the declared policy of the Congress that the Government should aid, counsel, assist, and protect, insofar as is possible, the interests of small-business concerns in order to preserve free competitive enterprise, to insure that a fair proportion of the total purchases and contracts or subcontracts for property and services for the Government (including but not limited to contracts or subcontracts for maintenance, repair, and construction) be placed with small-business enterprises, to insure that a fair proportion of the total sales of Government property be made to such enterprises, and to maintain and strengthen the overall economy of the Nation.[21]

This national policy, which reflects the intent and will of the Congress, is implemented through various provisions in the FAR regulations. For example, FAR § 19.201(a) states: "It is the policy of the Government to provide maximum practicable opportunities in its acquisitions to small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. Such concerns [small, disadvantaged, or women-owned businesses] shall also have the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency, consistent with efficient contract performance."[22]

Consistent with this policy, government contracting officers are required to include clauses entitled "Utilization of Small Business Concerns"[23] and "Small Business Subcontracting Plan"[24] in various solicitations and contracts. Undoubtedly, the policy to favor small business concerns and the interests of socially and economically disadvantaged businesses must be considered "to the fullest extent consistent with contract performance."[25] Under the subcontracting clause, a bidder must propose a subcontracting plan that includes, among other things, goals for subcontracting dollars to be spent related to small and small disadvantaged businesses and a description of the bidder's efforts to ensure that such businesses will have an equitable opportunity to compete for subcontracts.

In sum, the policy of the federal government, as reflected in both the Small Business Act and the FAR, is to provide small and small disadvantaged businesses with a fair opportunity to participate in federal procurements of all types. Such participation is essential to the continued growth of the national economy and, as stated in the Small Business Act, to the security of the United States. Any

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[21] *See* 15 U.S.C. § 631(a).
[22] *See also* FAR § 19.202-1 ("Small business concerns shall be afforded an equitable opportunity to compete for all contracts that they can perform to the extent consistent with the Government's interest.").
[23] *See* FAR § 52.219-8.
[24] *See* FAR § 52.219-9.
[25] *See* FAR § 52.219 8(b).

proposal that would eliminate or minimize such opportunities, such as a proposal that would waive, on a blanket basis, the FAR provisions discussed above and other FAR provisions requiring the participation of such small businesses, would be contrary to, and undermine, this longstanding and important national policy. It also would reduce competition, limit the number of bidders, and thereby operate to undermine the effectiveness of competitive bidding.

B. Monitoring Beneficiary Satisfaction With CBICs

Bayer encourages CMS to specify clearly in the final rule or require CBICs to identify the necessary telephone and internet resources that beneficiaries may use to raise questions and concerns related to the competitive bidding program. It is extremely important that beneficiaries have readily available access to information during their transition from their former suppliers to their new contract suppliers. Beneficiaries must be able to report the myriad of difficulties that they may face as the DMEPOS competitive bidding program is implemented for the first time, including problems with locating a new supplier or service quality concerns. We believe that the risk of negative press reports, even despite CMS' excellent efforts to launch this program, concerning the competitive bidding program will be significantly reduced if such contact information is readily available and apparent to the beneficiary population.

In addition, we strongly recommend that CMS establish a survey mechanism so that beneficiaries will be able to rate their satisfaction with the suppliers that they have chosen, as recommended by the September 2004 GAO report. While the Proposed Rule states that CMS may make available information on products for which suppliers will give rebates, it fails to provide a method to obtain feedback from beneficiaries regarding their satisfaction level with their contract supplier and disseminating this valuable information to other beneficiaries. Providing this information regarding the quality of service will assist beneficiaries in making an informed choice when deciding who they would like to fill their DMEPOS needs. The GAO report on competitive bidding recommended CMS' adoption of a survey program and stated that "routine monitoring of beneficiaries' concerns, complaints, and satisfaction can be used as a tool to help ensure that beneficiaries continue to have access to quality items."[26] We agree that such an evaluation system is essential to maintaining high quality of care long-term. Without such feedback, CBICs will be ill-equipped to judge, and thus monitor, either the quality of products that suppliers are providing or the accessibility of needed supplies to beneficiaries.

[26] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 17.

IV. Opportunity for Networks (Proposed § 414.418)

The Proposed Rule allows suppliers to form networks in order to submit a single bid for certain product categories. We commend CMS for proposing various opportunities to encourage the participation of smaller suppliers in the competitive bidding program. We are encouraged by CMS' willingness to consider suggestions regarding various aspects of forming potential networks, including the types of legal entities that should be allowed to submit single bids for a product category under the competitive bidding process. We appreciate CMS' concerns regarding anti-competitive issues and value its efforts to ensure that networks will be formed in an appropriate, efficient fashion that serves the needs of beneficiaries. However, significant changes to the proposed networking rules are necessary to make them viable and effective.

A. Support for Conditions That Networks Must Satisfy

1. *Independent Eligibility to Bid*

We generally support CMS' articulated conditions for potential networks that are considering the submission of a single bid. In particular, we support the requirements that each member independently must be able to comply with all necessary accreditation and quality standards. We believe this rule is important to retain in the final rule.

2. *Financial Standards*

We believe that, consistent with the antitrust guidance regarding financially integrated joint ventures, CMS should permit networks, whether through appropriate insurance or otherwise, to meet the applicable financial standards on a network basis. This will permit smaller suppliers a meaningful opportunity to participate. By increasing the number of potential bidders, this modification will further ensure cost savings.

3. *Need for Further Safeguards to Ensure Quality Service and Items*

We believe CMS should implement further safeguards to prevent networks from being formed that do not provide beneficiaries with quality service and items. We urge CMS to closely analyze bids submitted by networks to verify that the information collected and provided accurately reflects the services available across the bidder's geographic area of operation.

B. Reservation of Network Provisions for Smaller Suppliers and Problems with the Twenty Percent Limitation

As written, the network provisions are not adequately reserved as a mechanism for smaller supplier bidding. Small suppliers should be the focus of the network provisions because such a focus would increase the pool of bidders, help to reduce program costs, and reflect the intent of Congress. We seek CMS' clarification on whether the network provisions apply to big suppliers or chains, given the ambiguity on the face of the Proposed Rule.

The Proposed Rule and the twenty percent limitation ignore the dynamic nature of these markets and appear to be designed to punish the suppliers who are most successful at meeting the needs of consumers. For example, if Network A is created in the first year of competitive bidding from suppliers who collectively have nineteen percent of the market, and Network A outperforms all of its competitors such that thirty percent of consumers choose to buy from it, it would appear that the "reward" for excellent service would be to require the break up of Network A in the second year of the competitive bidding program so that Network A's Medicare market share does not exceed the twenty percent ceiling.

The notion of an across-the-board twenty percent ceiling for networks is itself inconsistent with antitrust doctrine. Although antitrust review is highly dependent upon the facts found in specific markets, federal antitrust agencies have often acknowledged that, in various situations, market shares much higher than twenty percent pose no serious risk of anticompetitive conduct or consequences. CMS should set forth a sliding scale that exceeds twenty percent dependent upon various factors (such as the size of the independent entities in the market with which the network must compete) or permit networks to participate above twenty percent on an assumption of the antitrust risk basis.

C. Allowing Network Members to Bid Individually

Possible network members should not be forbidden from also bidding individually. This limitation on allowing network members to bid individually, in effect, discourages smaller suppliers from using the network option. This proposal, furthermore, poses a risk of threatening the ability of competitive bidding from being implemented in any area that does have network bids, as failure of the network bid could lead to the exclusion of so many suppliers as to deny CMS the necessary number of suppliers to serve the area adequately.

D. Providing Appropriate Time to Allow Small Suppliers to Create Networks and More Antitrust Guidance

Exploring the idea of establishing networks and coordinating such efforts will be an extremely time-consuming process. It is vital that CMS provide

adequate time for implementation of the networking provision. Small suppliers must not only locate appropriate networking partners but they must also select an entity that will coordinate the price information in a manner consistent with antitrust laws.

The current antitrust rules appear to require small suppliers to employ a "messenger model" in which a third-party will serve as the data collector that would not release the prices offered by other members of the network. We seek further clarification from CMS regarding the need to use a messenger model. We request that CMS work with antitrust authorities to provide additional guidance that would allow unimpeded financial and clinical integration of networks.

V. Physician Authorization/Treating Practitioner (Proposed § 414.420)

The Proposed Rule authorizes the Secretary to establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if that physician or treating practitioner determines that use of that particular item would avoid an adverse medical outcome for the patient. When a specific item or mode of delivery is requested, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in locating another contract supplier within the competitive bidding area ("CBA") that can provide the particular item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery. The Proposed Rule requires the physician or treating practitioner who is willing to revise the order to memorialize it in a revised written prescription.

Bayer is supportive of a mechanism to allow physicians or treating practitioners to tailor medical treatment to specific patient needs by recommending specific products or modes of delivery. Indeed, we believe that this element of the proposal is absolutely essential to the appropriate implementation of competitive bidding and, particularly, the implementation of the program in a fashion that ensures a minimally acceptable level of quality. This mechanism is required to ensure that quality DMEPOS products become available to beneficiaries with variable medical needs.

The differences in glucose monitors, for example, can be critically important for many Medicare beneficiaries. Health care professionals consider many factors when selecting a diabetes care management system for a beneficiary with diabetes. These factors include the amount of blood required to perform a test if the beneficiary has difficulty obtaining a blood sample, the test strip size if the beneficiary has dexterity problems, the blood hematocrit range of the test if the beneficiary has a medical condition causing a low blood hematocrit, the size of the system display if the beneficiary has visual acuity problems, and data management features if the beneficiary has difficulty manually recording results. Unless the health care professional is able to choose the product that the health care professional

believes best serves the needs of the beneficiary with diabetes, the ability of the beneficiary to comply with the diabetes care treatment plan set forth by the health care professional is at risk. Given the limitation on multiple purchases of monitors in a given period under current DMEPOS policy, this would effectively result in many beneficiaries not having their needs met.

Thus, this type of consequence, the hindrance or failure of the patient's ability to comply with a diabetes care regimen, clearly constitutes an adverse medical outcome for patients with diabetes. We are concerned that contract suppliers will not appreciate or ignore the significant health impact that a particular type of blood glucose monitor will make on a certain beneficiary, particularly those with manual dexterity or visual impairments. CMS has the obligation to explain to the contract suppliers what constitutes an "adverse medical outcome" as part of its overarching mandate to protect beneficiary welfare and their access to essential medical products. This is consistent with CMS' actions in the Medicare Part D context where CMS was careful to explain to Part D contractors what CMS' expectations were in relation to appropriate beneficiary care such that Part D contractors could implement only limited cost control measures so as not to jeopardize the quality of services and access to necessary products. We request that CMS explicitly state in the final rule that the differences in diabetes care products may help avoid adverse medical outcomes for certain beneficiaries with diabetes under appropriate physician supervision and judgment.

In order for the protection afforded to beneficiaries by this provision to work appropriately and as intended, CMS must ensure that physicians or treating practitioners will be able to request an item through a simple process that is not burdensome to the physicians or treating practitioners. If the process used to implement this safeguard is burdensome, the process will discourage use of the safeguard and, thereby, result in the very problems that the safeguard was intended to prevent in the first instance.

VI. Rebate Program (Proposed § 414.416(c))

CMS proposes that contract suppliers that submitted bids for an individual item below the single payment amount should be permitted to provide beneficiaries with a rebate. The rebate may be equal to the difference between their actual bid amount and the single payment amount. The proposal does not contain provisions that condition the receipt of rebates on the financial need of beneficiaries, so there are no restrictions on which beneficiaries might receive the rebates. In addition, the proposal does not limit the amount of the rebate, other than stipulating that it not exceed the difference between a supplier's bid price and the single payment amount for that item. Thus, there is no correlation between the amount of the rebate and the beneficiary's co-payment or deductible. No proposition is in place to ensure that the rebate does not exceed the beneficiary's expenses.

While we appreciate CMS' laudable goal of trying to minimize beneficiary expenses, we think that the proposal should not be adopted. We have serious concerns about the implementation of Section 414.416(c). We believe that this proposal should be abandoned because it presents unacceptable fraud and abuse risks and will undermine the ability of successful bidders to compete on an equal basis.

The provision lacks any mechanism for ensuring that these rebates do not constitute an inducement for beneficiaries to use services unnecessarily or to favor certain providers over others in violation of both the Anti-Kickback Statute and the Anti-Beneficiary Inducement/Civil Monetary Penalty Provision. The proposed provision is simply and flatly inconsistent with the policies articulated by Congress, CMS, and OIG as expressed repeatedly in statutes, regulations, advisory opinions, and fraud alerts.

We believe that providing beneficiaries with monetary rebates will lead to increased utilization and spending, depriving the Medicare program of the very savings competitive bidding is designed to achieve. The use of rebates is fundamentally inconsistent with the cost-saving rationale that led Congress to pass the competitive bidding provision.

A. Good Faith Financial Need for a Waiver of a Co-Payment to Avoid Civil or Criminal Penalty

The provision of rebates or other remuneration to beneficiaries by healthcare suppliers or providers may violate civil and criminal statutes if it has the effect of influencing a beneficiary's choice of supplier or provider. Under the Anti-Kickback Statute, remuneration of any kind is prohibited if it is intended to reward or induce any order of any item payable under a federally funded health care program, including the Medicare program.[27] Allowing contract suppliers that bid below the single item payment amount to give cash rebates to beneficiaries will inevitably violate this basic criminal law. Although the OIG has permitted the waiver of patient obligations in situations where there is good faith financial need on the part of the beneficiary, the rebate provision is not in any way focused on such circumstances.

Similarly, the Anti-Beneficiary Inducement Prohibition imposes civil penalties on anyone who "offers to or transfers remuneration to any individual eligible for benefits... that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service."[28] Clearly the proposed rebates would affect the choice of supplier. Although the Civil Monetary Penalty provision, like the Anti-Kickback

[27] *See* 42 U.S.C. § 1320a-7b.
[28] *See* 42 U.S.C. § 1320a-7a(a)(5).

Statute, does not apply to good faith financial need waivers, that exception simply cannot justify the CMS proposal.

B. CMS' Position on Beneficiary Remuneration

In a wide variety of contexts, CMS has consistently stated that the offer of remuneration to beneficiaries is inappropriate. CMS' proposed policy permitting rebates to beneficiaries in the absence of any bona fide financial need is particularly surprising, given the dearth of utilization controls at the disposal of the government in the DME context. CMS' competitive bidding proposal is flatly inconsistent with CMS' own recent rejection of need-based patient assistance offered by individual manufacturers in the Part D context, notwithstanding the presence of broad, alternative utilization controls in Part D.

Furthermore, the Proposed Rule allows rebates to be realized by beneficiaries as direct monetary payments. In other contexts, the provision of money or cash equivalents has been rigorously avoided and considered particularly problematic. For example, Medicare Part C's Medicare Advantage rebates do not constitute any direct transfers of funds to beneficiaries and are only applied to supplemental health programs.[29]

A hospital outpatient rebate, allowed under 42 U.S.C. § 1396r–8, is distinguishable from the current proposed competitive bidding rebate because its purpose is to lower co-payments closer to the standard percentage for co-payments for the same services when provided at other sites of service. CMS' current competitive bidding proposal, however, would eliminate all co-payments in some cases and would take the co-payment below the amount that would otherwise typically apply in every case. By eliminating or substantially lowering the financial contribution of beneficiaries, CMS will unintentionally but inevitably increase utilization and overall costs.

C. OIG's Position on Rebates Outside of a Good Faith Financial Need Context

The OIG has consistently advised that waivers of co-payments and deductibles in circumstances analogous to the proposal implicate the fraud and

[29]Section 1854(b)(1)(C)(ii) of the Social Security Act specifies that "A rebate required under this subparagraph shall be provided through the application of the amount of the rebate toward one or more of the following: (I) PROVISION OF SUPPLEMENTAL HEALTH CARE BENEFITS AND PAYMENT FOR PREMIUM FOR SUPPLEMENTAL BENEFITS. . . (II) PAYMENT FOR PREMIUM FOR PRESCRIPTION DRUG COVERAGE. . . (III) PAYMENT TOWARD PART B PREMIUM." The Corresponding regulation, 42 C.F.R. § 422.266, mirrors the language of the statute. It states that "[t]he rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following: (1) Supplemental health care benefits. . .(2) Payment of premium for prescription drug coverage. . .(3) Payment toward Part B premium." 42 C.F.R. § 422.266(b).

abuse laws.[30] One fraud alert, targeted toward beneficiaries, warned Part B participants to "be wary of 'no out-of-pocket expense' offers," and specifically stated it was aimed at providers who "routinely waive Medicare deductible and co-payment charges."[31] OIG has also issued several advisory opinions regarding waiver of co-payments that consistently state that such waivers implicate the fraud and abuse laws.[32] Yet, this practice the OIG has identified to be problematic is exactly what the Proposed Rule would allow some suppliers to do if they happened to bid below the single payment amount.

In summary, the proposed rebate provision is inconsistent with current policy as it is expressed in the applicable statutes, regulations, and enforcement guidance. It should be rejected because it will lead to increased utilization that will decrease the savings competitive bidding may otherwise generate for the Medicare program.

VII. Authority to Adjust Payments in Other Areas (Proposed § 414.408(e))

CMS proposes to use the payment information determined under the competitive bidding program to adjust the payment amounts for the same DMEPOS in areas not included in the competitive bidding program for covered items furnished in 2009.[33] The proposed rule also states the possible general criteria CMS will use when deciding whether to exercise its authority under Section 1834(a)(1)(F)(ii) of the Social Security Act, which allows CMS to determine if such a course of action would be prudent. The criteria CMS will utilize to determine if it will use competitive DMEPOS prices to adjust prices outside of the bid areas are: (1) the savings needed for particular covered items and (2) the basis for adjustment including both the starting point for any such adjusted price and the method for adjustment. The Proposed Rule does not contain the specific methodology that would be used to adjust payments in other areas.

A. Summary of Bayer's Suggestions

We do not believe that CMS should attempt to use prices from within competitive bidding areas in areas that have not been bid competitively. While use of competitive bid prices outside of bid areas appears to be a plausible way of

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[30] The OIG issued a special fraud alert that unequivocally stated that providers who routinely waive Medicare co-payments may be held liable under the Anti-Kickback Statute. *See* 59 Fed. Reg. 242 (1994). This statement was reaffirmed in a later OIG Advisory Opinion, No. 97-4 (Sept. 1997).

[31] *See* HHS OIG Special Fraud Alert: Routine Waiver of Copayments and Deductibles Under Medicare Part B (May 1991).

[32] *See, e.g.,* OIG, Advisory Opinion No. 97-4 (Sept. 1997) (stating that the failure of a company to attempt to collect co-payments from beneficiaries, where an employer insurer refused to pay them, would be a violation of the Anti-Kickback Statute and Beneficiary Inducement Statute).

[33] *See* 71 Fed. Reg. 25654, 25664 (May 1, 2006).

securing additional savings in theory, in fact it would be very difficult to actually translate bid prices into economically sound prices for use outside of the competitive bid areas. This is because there is no principled way to account for the economic and other differences between competitively bid and non-competitively bid areas.

Even geographically contiguous competitive bid areas that are demographically similar will serve as a poor bases for determining reimbursement for non-competitively bid areas, as the absence of competitive bidding is itself too great and too fundamental a difference. Failure to account for all of these economic factors by attempting to impose bid prices in areas that have not undergone competitive bidding will undoubtedly lead to the unintended result of inadequate access and poor quality of care. CMS also should consider how the lack of CBIC oversight and other educational or administrative resources, which are an inherent part of the activities in competitive bidding areas, will affect the ability of the suppliers to provide quality access for the deflated reimbursement rates. It is a dangerous policy to implement competitive bid prices without a competitive bid process that will bring the necessary safeguards to bear.

B. Competitive Bid Areas Will Have Fundamentally Different Economic Environments Than Areas That Have Not Been Through the Bidding Process

The payment amounts derived from the competitive bidding program are a result of calculations that suppliers will make in anticipation of a greater market share as a consequence of the reduction in the total number of competitors. During the bidding process proposed by CMS, a set number of suppliers is awarded the right to furnish the item to beneficiaries. Suppliers assume that they will experience an increased volume in sales by winning a competitively bid contract. Taking that assumption into account, suppliers will set prices with the understanding that the increased volume can help cover overhead and other fixed costs.

Conversely, the suppliers in areas that have not been through the competitive bidding process cannot be assured that the imposition of a lower price will result in an increased share of Medicare business. There is no way for CMS to eliminate competitors in these areas to compensate suppliers for the lower prices, without going through the bidding process. In fact, there is no way for CMS to know, without undergoing the competitive bidding process, if the suppliers in any given area can meet a higher demand even if some of their competitors chose to leave the market due to the lower prices. Nor is there any way for CMS to predict which suppliers will be able to meet demand at lower prices and still maintain a profitable business. These facts are critical to ensuring that quality products are accessible to all beneficiaries.

Another complicating factor is the high potential for the competitive bidding process to favor large national suppliers as winners in any given bid area

because they are most likely to have the resources to service the increased volume, even at the lower single payment amount. Unless CMS targets only non-bid areas that are also serviced by large national suppliers, it would run the risk of adjusting prices in local areas serviced by small, regional outlets based on bid prices submitted by a different supplier mix. This would be grossly unfair.

All of these differences must be accounted for when setting the price in non-competitive bid areas, even where prices in bid areas locally, regionally, or nationally are or appear to be similar. Due to the fundamentally different assumptions that were the basis of the payment amounts from the competitive bidding program, as discussed above, it is inappropriate to apply them to contexts where the underlying factors are absent. CMS should not rely upon a process and a group of safeguards in some areas where competitive bidding prices apply and then fail to adopt that same process and those same safeguards in other areas where CMS proposes to use those same prices.

Non-bidding areas are fundamentally different than those subject to competitive bidding. Suppliers in areas that have not been through the bidding process should not have the lower bid prices imposed upon them without the attendant increase in volume accomplished through the elimination of competitors, a process that ensures that requisite quality safeguards are in place, and a means to ensure that adequate numbers of suppliers will continue to serve the market, notwithstanding the lower prices.

C. The Mechanisms Suggested in the Proposed Rule Appear to Be Inadequate

The Proposed Rule suggests a percentage adjustment of actual bid prices to account for the differing economic circumstances. The Proposed Rule fails to set out the extent of the proposed adjustment or the nature of the criteria that would be applied in making the adjustment. The lack of basic clarity in the proposal prevents the submission of truly meaningful and substantive comments regarding this issue. However, we believe that a percentage adjustment in any form underestimates the complexity of imposing artificially determined prices onto a free market system.

There is no standard methodology for imposing such artificial prices on a previously supply and demand driven system. Though the prices in a non-bid area are stipulated by the fee schedule, the suppliers in any given area competing for DMEPOS business are those that are able to provide product at the bid price. CMS has no relevant precedence to draw from in applying this kind of adjustment. Certainly a flat percentage adjustment to a bid price will not adequately account for differences in the ability of suppliers in non-bid areas to provide products at prices that suppliers in competitive bid areas have selected.

In summary, the best way to realize needed savings for a given item in areas that have not been through the competitive bidding process is to implement the same competitive bidding process. Failure to do so will undoubtedly lead to quality of care and access issues that stem from artificially imposing prices from a foreign economic system onto a local system that operates in a fundamentally different way. There is no feasible way to account for the differences in economics that will lead to a stable and efficient market for the item whose price is transferred. CMS should not take a risk with such an important benefit by blindly proceeding to apply bid prices in non-bid areas despite the obvious economic and market barriers to carrying out this policy. Such a course of action would be contrary to CMS' mission to "protect and improve beneficiary health" and to "foster high quality care."[34] The only equitable way of applying these payment amounts to non-competitive bidding areas, for both suppliers and beneficiaries, would be for CMS to conduct competitive bidding in that area. Failure to proceed in this fashion runs an unacceptably high risk of leading to quality of care and access issues.

VIII. Requirement to Obtain Competitively Bid Items from a Contract Supplier (Proposed § 414.408(f))

CMS proposes that a beneficiary who is traveling from a CBA to another CBA will be required to obtain supplies from a contract supplier. If the beneficiary travels from a CBA to a region that is not covered by the competitive bidding program, the beneficiary will be required to obtain supplies from a supplier that has a valid Medicare supplier number. The payment to the supplier in either case would be based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence.

Bayer is concerned that suppliers across the nation will be affected adversely by this provision. The payment that a supplier may receive for a beneficiary that maintains a permanent residence in a CBA will be most likely lower than what they normally receive in reimbursement. In other words, Medicare suppliers that are providing services outside of the CBA will be forced to accept pricing that is lower than normal for servicing that beneficiary. Such non-competitive bidding suppliers will not have the increased volume to offset the lower pricing, as contract suppliers will within a CBA.

In an effort to minimize unfairness to the non-competitive bidding suppliers, CMS should compensate the supplier that is supplying a beneficiary who has traveled from a CBA to the supplier's region that is not covered by the competitive bidding program the fee schedule amount or, if applicable, the Federal Employee Health Benefit Program schedule amount. If CMS decides to proceed with applying the single payment amount, CMS should make every effort to educate

[34] *See* http://www.cms.hhs.gov/MissionVisionGoals/ (last visited Jun. 13, 2006).

non-competitive bidding suppliers regarding what to expect for payments in such situations. The education on non-competitive bidding suppliers will facilitate the ability of beneficiaries to access the equipment that they need and minimize the risk that non-competitive bidding suppliers will decline to provide services at those same rates in non-competitively bid areas.

IX. Evaluation of Bids (Proposed § 414.414(e)) – Need for Appropriate Technical Bidding Requirements

We recommend that CMS carefully review the capacity of suppliers and establish measures to examine the sustainability of bids.

A. Market Demand and Supplier Capacity (Proposed § 414.414(e))

The Proposed Rule is based upon the speculative proposition that it can accurately predict demand and supply conditions for numerous products in highly fluid and complex markets. Significantly, CMS and other federal agencies have not been able to make these predictions accurately in the past. For example, in the implementation of the Part D program, beneficiaries skewed the estimated demand and supply conditions by overstocking drugs out of concern that there would be unavailability of necessary drugs during the transition period. CMS has not provided any meaningful opportunity in this Proposed Rule to comment on this important question because CMS has not explained how it proposes to address these critically important issues of demand and supply.

A critical aspect of striking the appropriate balance between demand and supply is the capacity of individual contract suppliers to meet the variable needs of an increasing Medicare population. CMS should carefully determine the minimum capacity threshold that contract suppliers must be prepared to meet and consider incorporating an extra margin of 25 percent. This rate is reasonable because this cushion will avoid disruption of services if unanticipated circumstances, such as natural disasters, arise within a specific CBA. Without this additional cushion, it is possible that suppliers may be awarded bids without the ability to appropriately meet beneficiary demand over the course of the contract. Other, more qualified suppliers may be excluded from the program as a result.

Similarly, CMS should consider offering contracts to suppliers beyond the capacity threshold, whatever number that is, and identify supplies so that 125 percent capacity is served.

Once CMS has calculated a reasonable capacity threshold, we urge CMS to scrutinize individual bids to ensure that suppliers can meet the appropriate capacity standards. It should also examine the geographic distribution of contract suppliers within a CBA and secure an adequate number of suppliers to realistically service the entire bidding area. Beneficiaries' needs will not be adequately met if the

number of suppliers necessary to achieve capacity is evaluated by CMS in a manner that unduly restricts available distribution channels. In other words, CMS should consider not only if the supplier can serve the area but also how easily it will be for the beneficiary to actually reach the supplier.

To implement this review in a fair manner, we also request that CMS clarify the expectations related to evaluating "capacity." It is unclear to us whether CMS will be analyzing a supplier's capacity for each item in a product category or the highest volume item in a product category. Will CMS select a supplier who can meet the highest volume capacity in one item, but has significantly reduced capacity for another item in the same category? Given the uncertainty surrounding this important issue, we respectfully ask CMS to provide more information in its final rule.

B. Composite Bids (Proposed § 414.414(e))

The composite bid process creates incentives for a supplier to manipulate the system by submitting low bids on certain items and high bids on others to reach a favorable composite score. We urge CMS to carefully structure the composite bid process to minimize such opportunities for suppliers to present information that will yield a composite score not truly reflective of the costs or the type of services and items that will be provided. Otherwise, CMS may inadvertently exclude qualified suppliers.

We seek further clarification on these issues of demand, supply and sustainability in the final rule promulgated by CMS.

X. Determination of Competitive Bidding Payment Amounts (Proposed § 414.416(b)) – Single Payment Amount

The Proposed Rule contemplates a pivotal bid that would reflect the point at which an adequate number of potential contractors necessary to serve an area had been identified. Under the Proposed Rule, that number of bidders is then offered a contract that each bidder may either accept or reject. This presents the chance, even a likelihood, that the adequate number of suppliers determined by CMS will not, in fact, be available in a given competitive bidding area.

We are concerned that the median determination methodology proposed by CMS contains certain deficiencies that will result in disadvantaging suppliers who have submitted valid and appropriately supported bids. These suppliers will not receive adequate reimbursement to cover their operations in the competitive bidding program. The proposed methodology results in roughly half of the winning suppliers receiving less than they bid for a particular item. This, unfortunately, may translate into a payment level that is below what an excellent supplier offering the greatest capacity may be able to accept.

This methodology is inconsistent with the methodology utilized in the demonstration projects and we are unclear why CMS is rejecting that tested approach. In the demonstration project, each winning supplier received at least as much as the supplier bid. This approach is the least likely to unfairly disadvantage suppliers who submit fair and honest bids, and the most likely to encourage successful bidders to participate in the program. Consistent with the methodology applied in the demonstration projects, we recommend that CMS require that the winning supplier must receive, at a minimum, the payment level that the supplier has bid.

We are also concerned that the Proposed Rule does not provide a mechanism for CMS to examine the sustainability of bids. By this we mean an assessment of whether the bid amount reflects a legitimate estimate of the reimbursement necessary for a supplier to cover its cost during the entire contract period while meeting the relevant quality, delivery, service, scope and similar requirements of the program. A thoughtful review may reveal that the majority of supplier capacity is above the pivotal bid and that the single payment amount is not sustainable or reasonable. In order to address this issue, we recommend that CMS either: (1) perform an analysis that tests the sustainability of the bids before the unsustainable bids pollute the bid pool or (2) re-calculate the single payment amount based on bidders that qualify for and can perform fully under CBA contracts, even if a disqualified bidder was used to determine a pivotal bid.

XI. Nationwide or Regional Mail Order Competitive Bidding Program (Proposed § 414.410(d)(2))

CMS is currently considering the establishment of a nationwide or regional competitive bidding program for certain items such as diabetes-related testing supplies after January 1, 2010. CMS envisions the submission of competitive bids by mail order suppliers in 2010. The proposed implementation of a nationwide or regional mail order competitive bidding program for diabetes-related testing supplies raises patient benefit concerns and small supplier concerns, particularly in light of the lack of the required experience and expertise necessary to implement this proposal with any reasonable confidence. We are concerned that mandatory mail order service for diabetes testing supplies would severely limit patient choice and deny many beneficiaries functional access to these supplies. We also urge CMS to examine closely how a mail order competitive bidding program will affect small businesses.

A. Limited CMS Experience with Diabetes-Related Care Items in Competitive Bidding Program

Given that a number of the components of competitive bidding have not been included in the San Antonio and Polk County demonstration projects, including diabetes care management items, CMS simply has insufficient experience

to proceed with such an ambitious proposal. Significantly, even with respect to those items included in the prior demonstration projects, there is not any mail order channel experience for diabetes-related care items in the competitive bidding program. In light of the significant doubts that exist about CMS' ability to implement competitive bidding successfully, even in its essential, mandated elements, CMS should not unnecessarily complicate the implementation challenge it faces by adding a mail order component to that effort in a premature fashion without the benefit of needed experience and testing of that concept.

B. Impact on Beneficiaries

Broad, mandatory mail order programs for supplying diabetes testing supplies would not be convenient for *all* Medicare beneficiaries, and CMS should make every effort to retain patient choice in treatment options and furnishing of critically necessary supplies in the face of a diabetes epidemic. Contrary to the underlying assumption that mail-order delivery is a "convenience for beneficiaries" in the GAO report,[35] mail-order delivery is just one of multiple channels of distribution that beneficiaries choose to obtain their blood glucose monitoring supplies. The majority of patients obtain many of their diabetes care management supplies at retail pharmacies. We urge CMS to preserve the choices that beneficiaries currently have in the method through which they receive their vital medical supplies for the monitoring and treatment of their diabetes.

Mandatory replacement of all supplies such as test strips and lancets for Medicare beneficiaries through mail order suppliers effectively limits access to these critical items to the poorest and most vulnerable segment of the beneficiary population. As noted above in section I, patients with diabetes already encounter significant hurdles in obtaining adequate test strips and diabetes monitoring supplies and suffer avoidable health consequences.[36] Some Medicare beneficiaries do not have a regular place of residence with secured methods of receiving mail supplies. Other beneficiaries cannot successfully maneuver various phone numbers to seek assistance from mail order suppliers. Medicare beneficiaries greatly benefit from the personal counseling and disease therapy management provided by their retail pharmacists.

Bayer has significant concerns that the premature development of a mail order option will raise issues about the adequacy of patient education and counseling services, such that patient compliance and persistency may be undermined. We request CMS to conduct further studies to ascertain that implementation of such a program will not result in unintended consequences. If

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[35] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 14.

[36] Ian Urbina, *In the Treatment of Diabetes, Success Often Does Not Pay*, N.Y. TIMES, January 11, 2006.

CMS decides to proceed with the implementation of a mail order competitive bidding program for diabetes-related items, Bayer urges CMS to preserve options for beneficiaries for whom mail order would be difficult and to implement it on a voluntary basis only.

C. Impact on Small Suppliers

Furthermore, a nationwide mail order competitive bidding program will severely limit the participation of small suppliers who specialize in particular regions and lack the capacity to service patients across the nation. This will decrease the parties available to bid, which, in turn, will undermine the ability of competitive biding to secure cost savings.

There is also a concern that fruitful relationships between individual beneficiaries and their suppliers, such as local pharmacies, will be unjustifiably disrupted. Beneficiaries often rely on expertise provided by pharmacists who observe and point out any potential drug interactions and provide invaluable information beyond the dispensing of supplies or medication.

In sum, Bayer challenges the notion that mail order delivery is convenient for all beneficiaries and urges CMS to review carefully the impact that implementation of a nationwide mail order competitive bidding program will have on beneficiaries and small suppliers. Implementation of a broad, mandatory mail order competitive bidding program may jeopardize beneficiaries' access to diabetes-related testing supplies and, ultimately, raise the cost of the federal health care program as beneficiaries with diabetes suffer the ravaging effects of the disease without proper monitoring and access to testing supplies.

XII. Payment Adjustment to Account for Inflation (Proposed § 414.408(b))

CMS proposes to apply an annual inflation update to the single payment amounts established for a competitive bidding program. Beginning with the second year of a competitive bidding contract, CMS will update the single payment amounts by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding calendar year. This is consistent with the method that the DME fee schedule is updated. CMS believes that this proposal will obviate the need for a supplier to consider inflation in the cost of business when submitting its bids for furnishing competitively bid items under a multi-year contract.

While we appreciate CMS' efforts to address the inflation issue, we are concerned that application of an annual inflation rate to the single payment amounts will not adequately take into consideration other factors that may merit an increase in the single payment amounts. The use of the CPI index and not the more relevant CPI-health index will understate the relevant inflation. CMS has used specific

inflation rates in other contexts, as in the inflation factor with end-stage renal disease drugs as implemented in 2004, and should follow that precedent here.

We are also concerned how this inflation factor will apply to items that are currently under a freeze for fiscal years 2007 and 2008.[37] It is our understanding that diabetic testing supply costs are ineligible for inflation factor application since they are class II devices subject to the freeze imposed by statute.[38] We urge CMS to clarify whether the inflation factor would apply notwithstanding the prior restriction. We point out that the inflation freeze in the fee schedule context is distinct from the application of the inflation factor in the competitive bidding program. CMS needs to consider this in its entirety.

XIII. Change in Ownership (Proposed § 414.422(d))

Consolidation in the industry is inevitable as the competitive bidding program is implemented. Thus, the competitive bidding program needs to address this reality and allow for greater adaptability and flexibility in allowing suppliers to change ownership status. The current proposed Section 414.422(d) requires modification so as to avoid onerous restraints on changes of ownership involving contract suppliers.

The Proposed Rule, as it stands, fails to take into consideration the short time period in which acquisitions or mergers often occur in the marketplace. While we appreciate CMS' concern for an appropriate analysis of the change in ownership, we ask that CMS modify the current sixty-day prior notice requirement. Suppliers should have the flexibility to provide notice as the transaction closes or

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[37] *See* 42 U.S.C. § 1395m(a)(14)(H) for 2007— (i) subject to clause (ii), in the case of class III medical devices described in section 360c (a)(1)(C) of title 21, the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and (ii) in the case of covered items not described in clause (i), 0 percentage points; and
42 U.S.C. § 1395m(a)(14)(I) for 2008— (i) subject to clause (ii), in the case of class III medical devices described in section 360c (a)(1)(C) of title 21, the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and (ii) in the case of covered items not described in clause (i), 0 percentage points; and
42 U.S.C. § 1395m(a)(14)(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.

[38] *See* 21 C.F.R. § 862.1345 "Glucose test system. (a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. (b) *Classification.* Class II."

when the parties sign a letter of intent if the transaction is due to close in less than a sixty (60) day period.

A successor entity should be allowed to continue supplying beneficiaries in a CBA as the winning contract supplier as long as it meets the general requirements for contract suppliers. While we appreciate CMS' concerns and desire to retain discretion to terminate a successor entity's contract with CMS for failure to comply with the general requirements, we do not think such broad discretion is warranted or consistent with ensuring appropriate access. The removal of any supplier determined to have been necessary to ensure adequate access at the time that contracts are entered into runs the inevitable risk that there will be insufficient suppliers to meet the necessary demand. This risk is unacceptable and unfair where a successor entity is willing to comply with the requirements of the applicable competitive bidding contract.

XIV. Quality Standards and Accreditation (Proposed § 414.414(c))

CMS notes in the Proposed Rule the statutory mandates limiting the award of a contract to entities that fully comply with the quality standards specified by the Secretary. CMS plans to further clarify quality standards at a later time. Bayer fully supports CMS' efforts to award contracts only to suppliers that fully comply with all accreditation requirements and quality standards but encourages CMS to implement the competitive bidding program only after the application of the relevant standards. Quality standards are an important part of CMS' effort to reduce fraud and abuse within the DMEPOS industry and ensure that beneficiaries are receiving high quality items and services.

Bayer, however, does urge CMS to provide further clarification regarding the quality standards that will be relevant to competitive bidders. Stakeholders have had to respond to the Proposed Rule regarding competitive bidding without having had the benefit of knowing the final quality standards. In order for suppliers to submit accurate bids under competitive bidding, suppliers need to be able to identify all fixed and variables costs in order to accurately determine a bid price for competitive bidding. It is unreasonable to expect a supplier to be able to quantify the additional costs incurred by compliance with the new quality standards without having adequate knowledge and experience with the financial reporting, quality standards, and accreditation requirements. CMS should not implement competitive bidding until the quality standards have been fully established and applied.

To allow greater and more substantive dialogue within the industry and medical community, CMS should set a second comment period to allow suppliers to evaluate how the newly issued quality standards will work in conjunction with the competitive bidding program.

XV. Establishing Payment Amounts for New DMEPOS Items (Gap-Filling) (Proposed § 414.210(g))

Bayer is concerned about the broad implications of the changes to the gap-filling process under the Proposed Rule and urges CMS to have a separate comment period to address the complex issues surrounding the gap-filling methodology. Bayer also requests that new technology be excluded from the competitive bidding cycle in which the product is introduced.

CMS has no formal process for establishing reimbursement amounts for new DMEPOS items. Currently, when a new DMEPOS item is introduced, CMS uses an informal and somewhat crude "gap-filling" process to determine the fee schedule rate. Since the product typically has no available historical pricing data, this crude process estimates what the average reasonable charges would have been for the item if Medicare had provided reimbursement during the fee schedule base period. The gap-filled base fees are updated by the covered item updates and are subject to regional fees, and ceiling and floor limitations. In certain circumstances, CMS may calculate the current payment amount by deflating the price of the product and then essentially re-inflating it.

CMS is proposing to establish a formal gap-filling process in the Proposed Rule. This proposal is a significant change to the existing, informal practice. Among other things, CMS plans to discontinue the practice of deflating supplier prices and manufacturer suggested retail prices to the fee schedule base period. CMS also plans to use a functional technology assessment process.

While we support CMS's desire to formalize this process, we strongly encourage CMS to undertake a separate notice and comment period to allow suppliers and other stakeholders to fully address the complicated issues related to this proposal. The changes CMS is proposing and the impact they have on the Medicare DMEPOS fee schedule and the competitive bidding program are significant. The Proposed Rule is not the appropriate place for this discussion.

In addition to our general concern about the timing of this topic, we also believe it is inappropriate for CMS to include new technology and new items, even if subject to a reasonable gap-filling process, in the competitive bidding program. Suppliers did not consider the availability or costs of these items when calculating their bids. It is unfair and unreasonable to assume that these new items will have no material impact on direct and indirect supplier costs. Instead, we recommend that CMS exclude the new technology from the competitive bidding cycle in which the product is introduced or for a defined period of two years after the product is brought to market.

This approach is consistent to what CMS has done in other contexts. When new technology is introduced into the market, there is an inevitable passage

of time before the medical and patient communities accept and integrate the new technology, and the operational costs and benefits are fully realized. To reflect the ordinary course of market acceptance, CMS should not arrive at a gap-filled price immediately after an item is introduced into the market, nor should the item be inserted into the list of products subject to competitive bidding. This slight deferral of inclusion of the new technology is analogous to the management of new technology in the hospital inpatient and outpatient payment systems. In this context, CMS has created temporary APC pass through payments based on acquisition costs to reflect the higher cost of the new technology. These rates are used until such time as that technology can be assessed and the payment rate created under the standard methodology.

For ease of administration, we urge CMS to exclude this new technology from the competitive bidding cycle in which the item is introduced or two years, whichever is longer. We suggest CMS similarly delay calculating the new payment rate for the item under the Medicare fee schedule.

XVI. Payment Basis (Proposed § 414.408)

The Proposed Rule does not appear to contemplate an emergency exception in which beneficiaries may obtain supplies from their original suppliers for a short duration of time under limited circumstances. Bayer is concerned that a grandfathered supplier or a non-contract supplier will refuse to assist the beneficiary who lives within a CBA. The proposed grandfathering provision does not apply to patients with new medical needs and the proposed payment basis provisions do not address situations in which a beneficiary is in dire need of an item or service and is not able to be immediately assisted by the new contract supplier. Thus, we recommend that CMS establish an emergency exception that allows beneficiaries to receive supplies from their current supplier even after the commencement of the competitive bidding program for a short period to ensure that beneficiaries do not have a disruption in their services or supplies.

XVII. Conclusion

We thank CMS for its tremendous efforts in implementing the competitive bidding program in a fair and effective manner. We appreciate this opportunity to share our thoughts and concerns with you. We are happy to discuss any of these issues and welcome any questions that you may have.

Sincerely,

Sandra S. Oliver
Head of Public Policy &
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cc: Herb Kuhn
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Mark B. McClellan, M.D.
Administrator
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Baltimore, MD 21244-8013

Re: **Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues [CMS-1270-P]**

Dear Dr. McClellan:

The Electrical Bone Growth Stimulator (EBGS) Coalition appreciates this opportunity to provide specific comments on a provision included in subpart M of the background section of the Notice of Proposed Rulemaking entitled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, [CMS-1270-P]" published in the *Federal Register* on May 1, 2006.

The EBGS Coalition is comprised of the three leading manufacturers of external bone growth stimulator devices (noninvasive osteogenic stimulators), which are classified as class III devices under section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act. Our coalition members are Orthofix Incorporated, EBI, and DJO Incorporated (formerly dj Orthopedics, Inc.). Coalition members currently represent 100 percent of the American market for osteogenic stimulators. These devices are used to treat nonunion fractures of the appendicular skeletal system, congenital pseudarthrosis, failed fusions of the appendicular system and to serve as an adjunct to spinal fusions. These devices are all classified by the Food and Drug Administration (FDA) as class III devices and must receive premarket approval by FDA to ensure that they are safe and effective before they can be marketed.

Orthofix Incorporated, a global diversified orthopedic products company, offers a broad line of minimally invasive surgical, as well as non-surgical, products for the spine, reconstruction, and trauma market sectors that address the lifelong bone-and-joint health needs of patients of all ages—helping them achieve a more active and mobile lifestyle. Orthofix Incorporated's products are widely distributed around the world to orthopedic surgeons and patients.

EBI is a pioneering global leader in electro and biomechanical medicine and one of six strategic business units of Biomet, the fifth largest producer of orthopaedic products worldwide. EBI designs, develops, manufactures and markets products used primarily by orthopaedic medical specialists in both surgical and non-surgical therapy. EBI features innovative electrical stimulation and external fixation devices, in addition to a comprehensive line of spinal and orthopaedic support products.

DJO is a global medical device company specializing in rehabilitation and regeneration products for the non-operative orthopedic and spine markets. Marketed under the DonJoy, ProCare, and Aircast brands, the Company's broad range of over 600 rehabilitation products, including rigid knee braces, soft goods, and pain management, are used in the prevention of injury, in the treatment of chronic conditions and for recovery after surgery or injury. The Company's regeneration products consist of bone growth stimulation devices that are used to treat nonunion fractures and as an adjunct therapy after spinal fusion surgery. Together, these products provide solutions throughout the patient's continuum of care.

THE PROPOSED RULE PROVIDES NO SPECIFIC PROPOSAL FROM THE AGENCY ON CLASS III DEVICES

In background Section I, Subpart M of the May 1st proposed rule, CMS solicits comment on how to determine the appropriate payment update percentage for class III devices in 2007 and 2008.[1] CMS in its proposed rule offers no specific payment update proposal on which to comment. The Coalition asserts that a full CPI-U payment update is warranted in 2007 and 2008, as discussed below. The Coalition also looks forward to working with the agency to provide additional comments on an appropriate update percentage for class III devices.

CONGRESS PROVIDED SEPARATE AND UNIQUE PAYMENT UPDATES FOR CLASS III DEVICES

Section 302 of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) provides for a distinct payment update for class III devices in 2004 through 2006 that differs from the payment update for class II devices and specifically excludes class III devices from competitive bidding. For class III devices, the MMA states that the payment update for 2004 through 2006 should be the percentage increase in the CPI-U for the year involved. The MMA further mandates that the Secretary has the authority to determine the appropriate payment update for 2007. In 2008, the payment update is set in statute at the percentage increase in the CPI-U.

The following provides additional information regarding our comments and recommendations.

1. CMS SHOULD FOLLOW CONGRESSIONAL DRECTION AND PROVIDE A SEPARATE PAYMENT UPDATE FOR CLASS III DEVICES FOR 2007

The Coalition urges the Secretary to establish a class III device payment update for 2007 based upon factors unique to class III devices. In order to assist the Secretary in setting payment updates for class III devices, Congress directed the GAO to conduct a study containing recommendations on the appropriate update percentage for class III medical devices furnished to Medicare beneficiaries in 2007 and 2008. In 2008, the MMA

[1] 71 Fed. Reg. 25,654, 25660 (May 1, 2006).

establishes a payment amount equal to the 2007 payment, increased by the percentage rise in the CPI-U. For subsequent years (*i.e.*, 2009 and later), the MMA provides for a payment update of the CPI-U for class III devices.

In contrast to the payment updates provided to class III devices, the MMA subjected class I and class II durable medical equipment to a payment freeze for five years (*i.e.*, zero percentage update), from 2004 through 2008. In addition, the MMA established a competitive acquisition program for certain class I and class II devices that fall within certain specified categories, beginning in 2007. Congress chose to differentiate between most class II and class III devices in providing class III devices a payment update and exempting them from competitive bidding in part because it believed that there are important differences in clinical complexity and ongoing costs associated with class III devices that would warrant these differential treatments.

2. GAO REPORT ON CLASS III DEVICES DOES NOT PROVIDE NECESSARY GUIDANCE TO THE AGENCY FOR AN APPROPRIATE PAYMENT UPDATE

In Subpart M of the background section, the proposed rule states that CMS will consider the recommendations in the GAO report in determining the appropriate update percentage for class III devices in 2007 and 2008. However, the GAO report did not provide an update percentage for class III devices as specifically mandated by Congress in the MMA. It is unfortunate that the GAO missed an important opportunity to provide CMS with guidance on an appropriate payment update percentage for class III medical devices. Furthermore, the GAO report failed to consider the clinical complexity of class III devices and the factors unique to class III devices that contribute to changes in ongoing and future costs and which are not captured in the initial retail price of such devices. Such ongoing costs include continuing regulatory obligations, labor, continuous product improvement, and service components necessary to ensure positive health outcomes for the Medicare beneficiaries who use these devices. These ongoing costs and clinical complexities warrant an appropriate payment update separate from competitive bidding.

3. COALITION COMMENTS REGARDING SPECIFIC PAYMENT UPDATE PERCENTAGE FOR CLASS III DEVICES IN 2007 AND 2008

An appropriate update factor for class III devices should reflect the unique and ongoing costs associated with providing these complex medical devices to a vulnerable patient population. Noninvasive osteogenic stimulators account for over 95 percent of the class III devices covered by Medicare Part B under the durable medical equipment benefit.

Often these devices are prescribed for patients who suffer from bone fractures or fusions that have otherwise failed to heal properly. In many instances, osteogenic stimulators provide a non-invasive treatment option that can avoid an initial (or additional) surgical intervention, which is especially important for Medicare's elderly and disabled patient populations. Fair and adequate reimbursement must exist to ensure that Medicare

beneficiaries continue to have meaningful access to these important class III devices.

Determining an Appropriate Update for Class III Devices

Bone growth stimulators are class III devices that require a great deal of patient-specific technical service. Each device must be designed and configured for the fracture being treated. This includes the need to calibrate these devices for each individual patient. These services are performed by technicians who are specially-trained by the manufacturer for each particular device.

The bulk of the costs for a class III device is not due to the manufacturing of the device itself. Instead, most of the costs associated with providing bone growth stimulators arise from the ongoing and labor-intensive services required to provide for the safe and effective use of these complex medical devices on a patient-by-patient basis. Approximately half of the total costs are attributable to these ongoing, specialized labor costs and other non-manufacturing personnel costs. In addition to these costs, the support and overhead costs related to appropriate distribution of these devices reflect a considerable percentage of the total costs.

Medicare payment updates have not adequately recognized the expected and reasonable increases in costs associated with supplying osteogenic stimulators to Medicare beneficiaries. For example, during the last decade (from 1996 to 2005), Medicare payment rates have not kept pace with the increases in costs of manufacturing and supplying these class III devices:

- Medicare payment rates for class III devices have increased by about 17 percent during the last decade.

- The specialized labor costs associated with supplying these devices (as measured by employee compensation for all workers) have increased by about 40 percent during the last decade.

- The distribution support and overhead costs (as measured by the CPI-U) have increased by about 28 percent during the last decade.

This comparison strongly suggests that a positive update is needed for class III devices in 2007. An update equal to the CPI-U will only partially close the gap between the increases in manufacturers' costs and Medicare payments. An update that is less than the CPI-U would be even more inadequate.

CMS Should Not Link Class III and Class II Updates

In its study, the GAO focused on how initial prices are established for class III devices under Medicare Part B as compared to a small, non-representative subset of class II devices. The GAO concluded that the initial Medicare payment rates for all classes of medical devices were set consistently by CMS based on retail prices or an equivalent measure.

The GAO missed a critical point that distinguishes class III devices from most other items of durable medical equipment. The underlying cost structure of supplying medically complex class III devices differs from the underlying cost structure for class II devices. As a result, aligning the Medicare updates for these two classes of devices is inappropriate.

The GAO did not include evidence to determine the appropriate Medicare payment update factor for class III devices in its study. In addition, the GAO study did not address the ongoing specialized labor and distribution support costs required to ensure the safe and effective use of these complex devices. As a result, CMS should not rely upon the GAO's conclusions for establishing future Medicare updates for class III devices.

In addition, the GAO did not examine other important and ongoing costs associated with the provision of these devices. For example, the GAO did not evaluate the ongoing research and development costs related to clinical improvements and new indications.

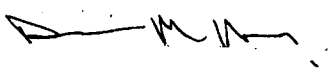
CONCLUSION

For the reasons stated above, we urge CMS to establish a positive update for class III devices in 2007 that takes into account the full costs of manufacturing and supplying these complex devices to Medicare beneficiaries. The GAO study is flawed, especially with respect to the GAO's failure to take into account the full and legitimate costs associated with supplying this labor-intensive therapy.

In light of these findings, an appropriate update for class III devices for 2007 should not be less than the CPI-U. Congress has highlighted the importance of ensuring that Medicare beneficiaries have ongoing access to class III devices under Medicare Part B. However, we are especially concerned by the lack of any proposal set forth by CMS in this notice, which frustrates our ability to provide meaningful comment.

We would welcome the opportunity to meet and communicate further with CMS on this important issue. Please do not hesitate to contact me at 202-898-6360.

Sincerely,



Denise M. Henry

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By Hand-Delivery

June 30, 2006

Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

CMS File Code: CMS-1270-P

RE: Comments Regarding Issues Raised in the Proposed Rule Regarding the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and Other Issues

Dear Dr. McClellan:

Orthofix Inc. ("Orthofix") submits the following comments in response to the Centers for Medicare and Medicaid Services' ("CMS") proposed rule related to the competitive acquisition of certain durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). See 71 Fed. Reg. 25,653 (May 1, 2006). The company's comments discuss the failure of the General Accountability Office ("GAO") Report to meet its statutory objective of providing supportable recommendations to the Secretary of the Department of Health and Human Services (the "HHS Secretary") and articulate why Class III devices deserve a full inflation update for 2007 and 2008.

Orthofix is a medical device company that specializes in surgical and non-surgical orthopedic products for the spine, reconstruction, and trauma market sectors. The company's products are designed to address the lifelong bone-and-joint health needs of patients of all ages, helping them to achieve a more active and mobile lifestyle. Orthofix designs, develops, manufactures, markets and distributes medical equipment used principally by musculoskeletal medical specialists for orthopedic applications.

I. Introduction

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") provided the HHS Secretary with the authority to determine the appropriate fee schedule update percentages for Class III Durable Medical Equipment ("DME") for CYs 2007 and 2008. Pub. L. No. 108-173, § 302(c)(1), 117 Stat. 2231 (codified at 42 U.S.C. § 1395m(a)(14)). The MMA also directed the GAO to submit a

report to Congress and to the Secretary with recommendations on the appropriate update percentages for Class III DME. Id. § 302(c)(1)(B). In March 2006, the GAO published the results of its study. GAO Report No. GAO-06-62 (March 2006). However, the GAO Report is methodologically flawed and fails to meet the Congressional objectives set forth in the MMA. As such, CMS should not rely on the GAO's findings when it sets the Class III payment rates.

At the outset of these comments, we emphasize that Class III devices (and particularly bone growth stimulators, which represent the vast majority of Medicare covered Class III devices) are fundamentally different from Class II devices. These products are technically complex and require ongoing cost outlays and services that are unnecessary for other devices. To ensure bone growth stimulators' effectiveness, technicians are specially trained to calibrate the device for an individual patient's needs.

A full inflation update for bone growth stimulators is warranted because of the costs arising from: 1) the regulatory burdens required to maintain a product's safety and effectiveness (a pre-requisite for Medicare beneficiaries); 2) the labor associated with appropriately servicing and training an individual to utilize a Class III device; and 3) the research and development and related fees required to innovate improvements in a device's effectiveness, including clinical trials. These substantial costs justify continuation of the modest inflation update policies that were established in the MMA.

II. CLASS III DEVICES SHOULD RECEIVE A FULL CPI UPDATE

As discussed above, most of the costs associated with the sale of bone growth stimulators arise from the ongoing and labor-intensive services required to provide for the safe and effective use of these complex medical devices on a patient-by-patient basis. Approximately half of the total costs are attributable to these ongoing, specialized labor costs and other non-manufacturing personnel costs. Additional costs are then incurred for support services and overhead costs related to appropriate distribution of these devices.

Unfortunately, Medicare payment updates have not recognized the expected and reasonable increases in costs associated with supplying bone growth stimulators to Medicare beneficiaries. During the last decade alone (from 1996 to 2005), Medicare payment rates have not kept pace with the increases in costs of manufacturing, servicing and supplying these Class III devices. While Medicare payment rates for Class III devices have increased by about seventeen percent during this time, the specialized labor costs associated with supplying these devices (as measured by employee compensation for all workers) have increased by about forty percent. Furthermore, the distribution support and overhead costs (as measured by the CPI-U) have increased by about twenty-eight percent during the last decade. This data strongly suggests that a positive update is needed for Class III devices in 2007.

III. Congress Differentiated in the MMA Between Class III Medical Devices and Devices that Require Less Regulation to Ensure Safety and Efficacy (Class I and II Devices)

In enacting the MMA, Congress noted the distinction that the Food and Drug Administration ("FDA") draws between categories of medical devices. H.R. Rep. No. 108-391, at 572 (2003). FDA classifies medical devices into three different classes (Class I, Class II, or Class III) depending upon the amount of regulation necessary to provide a reasonable assurance of safety and efficacy. 21 U.S.C. § 360c(a). Class III devices represent life sustaining or life supporting devices, or devices which otherwise present a potentially unreasonable risk of illness or injury, or are of substantial importance in preventing impairment of human health. Id. § 360c(a)(1)(C).

Congress recognized important differences between Class III and other devices in several specific ways in the MMA. First, Congress excluded these Class III devices from the competitive acquisition program for certain DMEPOS. 42 U.S.C. § 1395w-3(a)(2)(A). This exclusion was placed into the Conference Report (the earlier House version of the competitive bidding provisions had no such exclusion) because the Conferees fundamentally believed that the technical complexity and services required to assure the safety of these devices for Medicare beneficiaries warranted separate treatment. Significantly, no other specific exclusions for devices from the competitive acquisition program were included in the MMA despite aggressive efforts from industry.

Second, for purposes of determining payment updates, Congress distinguished between Class III and other devices. The MMA provides no payment update for other devices between 2004-2008. 42 U.S.C. § 1395m(a)(14). By contrast, Class III devices received an update for 2004-2006 and 2008 that corresponded to the consumer price index for all consumers ("CPI-U"). Id. For 2007, the payment update for Class III devices will be determined by the HHS Secretary, taking into account the GAO Report. Id.

The distinctions that the MMA draws between Class III and other devices reflect Congress' recognition that Class III devices are critical to patients' well-being and often necessitate larger investments from manufacturers. In addition, Class III devices frequently require considerable investments in time and resources for servicing to ensure peak performance in these life-supporting devices. The GAO Report, though, ignores many of these important differences and fails to achieve Congress' objectives.

IV. The GAO Report Uses an Inappropriate Analytical Construct that Compares Class III to Class II Devices

The GAO's broad statutory directive under the MMA was to make "recommendations on the appropriate update percentage" for Class III devices to be used for devices furnished in 2007 and 2008. Pub. L. No. 108-173, § 302(c)(1)(B), 117 Stat. at 2231. Rather than examining all costs borne by Class III devices to determine the appropriate payment update, the GAO Report compared whether the CMS schedule

rate-setting methodology accounted for the premarketing costs of both Class II and Class III devices, respectively.

This comparative approach inappropriately assumes that the payment update should be uniform for both Class II and Class III devices in the absence of significant differences in how the premarketing costs are incorporated into the CMS rate-setting methodology. Although not expressly stated, the GAO Report essentially adopts the position that Congress' payment freeze for Class I and Class II devices is also appropriate for Class III devices if all premarketing costs are accounted for in the rate-setting methodology.

This position is contrary to the intent of the MMA. The motivating rationale for the DMEPOS competitive acquisition program and the payment freeze for non-Class III devices was to align the prices that Medicare paid for DME with the prices observed in the marketplace and paid by other federal programs. In June 2002, the HHS Inspector General testified before a subcommittee of the Senate Appropriations Committee that "[o]ur price comparison demonstrates that Medicare overpays for some medical equipment and supplies."[1] A release by Chairman Bill Thomas of the Committee on Ways and Means referenced this Congressional testimony in highlighting provisions in the MMA Conference Report that established a transition to DMEPOS competitive bidding and enacted a multiple year payment freeze for many DME products.[2] Significantly, although the MMA Conference Report also references the June 2002 testimony of the HHS Inspector General, the Conference Report specifically excludes Class III devices from the competitive bidding provisions and provides separate payment updates for Class III devices. H.R. Rep. No. 108-391, at 575, 577-78 (2003).

Any analytical approach that assumes that the payment update should be based on a comparison between Class II and Class III devices is inappropriate. Congress clearly intended to treat these devices as separate categories for payment purposes. Thus, recommendations related to the payment update for Class III devices should focus on the cost structure of Class III devices – and not on a comparison with the costs associated with Class II devices. By not examining the complete cost structure of Class III devices and any increases, both real and inflationary, that would necessitate a payment update, the GAO Report failed to meet the statutory objective Congress set for it in the MMA.

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[1] Testimony of Janet Rehnquist, Inspector General, Department of Health and Human Services, before the Senate Committee on Appropriations, Subcommittee on Labor, HHS, and Education (June 12, 2002), available at, http://www.oig.hhs.gov/testimony/docs/2002/020611fin.pdf (last visited June 22, 2006).

[2] Committee on Ways and Means, "Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Medicare DME Freeze and Competitive Bidding Saves Beneficiaries and Taxpayers Money" (Nov. 19, 2003), available at, http://waysandmeans.house.gov/media/pdf/healthdocs/dmesummary.pdf (last visited June 22, 2006).

V. The GAO Report Fails to Consider Increasing Costs Borne by Class III Devices After the Initial Approval and Launch of the Product

Even if it were appropriate for the GAO Report to compare Class II and Class III devices in setting forth payment update recommendations, the Report is flawed in another significant way because it focuses on premarketing costs only. This narrow focus is improper given the GAO's broad statutory directive to provide recommendations to the Secretary about the appropriate payment update for 2007. Accordingly, recommendations related to the payment update must account for unanticipated cost increases that occur after a medical device has entered the market.

CMS' schedule rate-setting methodology is based on a manufacturer's retail price or historic reasonable Medicare charges from a base year, generally updated by an annual percentage. 42 U.S.C. § 1395m(a)(2), (14). When the only available price information is from a period other than the base period, a Medicare contractor must apply certain deflation factors to approximate the base year price for gap-filling purposes. Medicare Claims Processing Manual, Pub. 100-04, Ch. 23, § 60.3. The incorporation of premarketing costs into the base year price is critical to ensure that the CMS schedule rate-setting methodology adequately reimburses the costs associated with supplying a medical device.

Even so, an accurate base year price or approximation is only one piece of the reimbursement puzzle. Congress has also generally provided annual updates to the DMEPOS payment amounts. 42 U.S.C. § 1395m(a)(2), (14). These annual updates typically reflect the increases in the CPI–U. Id. At the very least, these increases reflect the inevitable increasing costs associated with inflationary pressures. Despite the fact that the CPI-U had increased over the previous year, the GAO Report does not address the need to provide a payment update to account for these post-marketing cost increases.[3]

In addition to cost increases stemming from inflation, Class III devices face other post-marketing costs that are not accounted for in the GAO Report. These costs include substantial regulatory expenditures not typically born by other devices. Class III devices are subject to premarket approval, 21 U.S.C. § 360e(a), and, under the Medical Device User Fee and Modernization Act of 2002 ("MDUFMA"), each premarket application ("PMA") or supplement generally must be accompanied by a user fee. Pub. L. No. 107-250, 116 Stat. 1588 (codified at 21 U.S.C. § 379i). Although the GAO Report observes that user fees paid in the premarketing period are likely incorporated into the base price of a device, the Report does not account for the difference in user fees paid in the post-marketing period for PMA supplements. The costs associated with

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[3] Congress set forth a specific methodology for other DMEPOS payment updates tied to the CPI-U. See 42 U.S.C. § 1395m(a)(14)(B), (D), (F). This methodology ties the payment update to the percentage increase in the CPI-U (U.S. city average) in the 12-month period ending with June of the previous year. Id. Based on data reported by the Bureau of Labor Statistics, the CPI-U index (U.S. city average) increased from 194.5 in June 2005 to 198.7 in February 2006 (1982-84 =100). Bureau of Labor Statistics, Consumer Price Index – All Urban Consumers, Series Id. CUUR0000SA0 (Not Seasonally Adjusted), available at, http://data.bls.gov/cgi-bin/surveymost

these supplements are significantly higher than those associated with Class II devices. For example, the user fee for a panel-track supplement for a Class III device is $259,600 and the user fees for a 180-day supplement and real-time supplement (Class III devices) are $55,814 and $18,691, respectively. 70 Fed. Reg. 46,872, 46,873 (Aug. 11, 2005).

The fees cited above are not incurred infrequently. The need for PMA supplements arises regularly, and the GAO Report does not capture these potentially significant regulatory fees.[4] For example, Orthofix's bone growth stimulator has been the subject of twenty-seven supplements since the PMA was approved on February 21, 1986. In the future, Orthofix will be required to pay user fees each time it files a supplement. These supplements are pursued to facilitate a product's safety and effectiveness and to improve patient compliance with a product.

The central premise of the GAO's recommendation to link the payment update of Class II devices to Class III devices is that the cost components for each of these classes will be built into the initial retail price of a product. That assumption is simply inaccurate, especially in the post-MDUFMA fee-paying environment. Today, if a company submits a supplement to the FDA, it will pay substantial user fees. These fees did not exist – and more importantly – could not have been anticipated at the time when Orthofix or other manufacturers of Class III products established their initial retail prices.

Additionally, these regulatory fees represent only one category of post-marketing costs that the GAO Report did not consider and that would support a positive payment update for Class III devices. As the GAO Report notes with respect to premarketing costs, PMA supplements may also require the submission of technical data which may require a significant volume of testing, clinical data, and extended review times that increase product costs. Because these costs are incurred after product launch, it would be difficult to predict these costs or to factor them into any base year price.[5] However, these costs are not trivial or unimportant.

Recently, an FDA Advisory Committee recommended that FDA not down-classify certain non-invasive bone growth stimulators after receiving extensive testimony regarding the technical expertise necessary to develop and design these Class III devices.[6] This recommendation confirms the distinct regulatory status of these Class III devices and the need for CMS and the GAO to carefully consider the post-marketing costs associated with them. As was stated by researchers and physicians alike during the recent FDA panel meeting, very small changes in the magnitude or other output

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[4] See FDA Website, CDRH PMA Database, available at, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=10195 (last visited June 22, 2006).

[5] The GAO Report asserts that costs incurred in the development of a new device "are premarketing costs related to that device and not costs related to marketing the existing device." GAO Report, at 13. However, the Report never explains why it failed to consider research and development costs associated with improving a device or developing new uses for the same device – costs that cannot necessarily be predicted or, if foreseen, adequately measured.

[6] Summary, Orthopaedic and Rehabilitation Devices Panel (Updated June 5, 2006), available at, http://www.fda.gov/cdrh/meetings/060206-summary.html (last visited June 22, 2006).

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June 26, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r)(3) to include podiatric physicians and insure that patient care is not harmed.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

Many of our members prescribe and supply select DMEPOS items as part of patient care. We do not supply items to individuals who are not our patients and believe that requiring us to do so would harm Medicare beneficiaries who are our patients. Our members have valid supplier numbers and adhere to the existing 21 supplier standards. We are subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As physicians in the Medicare program, we should have those same rights. We use DMEPOS items as an integral part of patient care and urge CMS to use the 1861(r)(3) definition of physician in finalizing its regulations.

Sincerely,

James P. Ioli, DPM, FACFAS
President

LAUREL
HEALTH CARE COMPANY

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June 21, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: 42 CFR Parts 411, 414, and 424 Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Dear Sirs:

I have reviewed the above proposed rule and have the following concerns:

- It appears the rule would be applied to all beneficiaries with Part B coverage, including those residing in a nursing facility.
- Most nursing facilities currently coordinate the acquisition and billing of DMEPOS necessary for the care of there patients. Nursing facilities serve as the DMEPOS supplier or arrange for services with a DMEPOS supplier.
- CMS has a track record of wanting nursing homes to be responsible for acquiring and billing all supplies and services necessary for its nursing home residents. The original Balanced Budget Act mandated Part B consolidated billing for nursing homes.
- CMS and the States hold each nursing home responsible for assuring that the right supplies are delivered to the right residents at the right time. Penalties are stiff when nursing facility residents do not receive prescribed supplies and services.
- Under the proposed rule, it would appear that nursing homes will be at the mercy of CMS contracted "low bidders" to provide the right supply to the right resident at the right time. I fear that these "low bidders" are going to be focused on the home care market and not the needs of nursing facilities or their residents.
- When the CMS "low bidders" fail to meet the need of nursing home residents, will CMS and States say "That's OK nursing homes, we won't hold you accountable for the substandard care afforded your residents"? Currently, nursing homes are held accountable for the actions of all outside suppliers and service providers.
- I strongly urge you to exempt nursing home residents from the DMEPOS low bid supplier process. At a minimum, allow nursing homes to match the average DMEPOS price as DMEPOS suppliers for their nursing facility residents.

Sincerely

Roger Obenauf
Director of Specialty Services

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June 12, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO BOX 8013
Baltimore, MD 21244-8013
Re CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as a Small Pharmacy for consideration as CMS develops the final regulation.

I strongly object to CMS'alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers; this restricts the beneficiaries' choice. The proposal would severely restrict beneficiaries' access to needed items and supplies (especially in rural areas) and may compromise patent health outcomes.

The competitive bidding program should NOT include common DMEPOS supplies such as diabetic testing supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the agency should limit the competitive bidding program to those unique products that could be provided by a central supplier.

I urge CMS to take steps to ensure that small suppliers which include the majority of pharmacy based suppliers who can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be compete in large metropolitan areas .After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.

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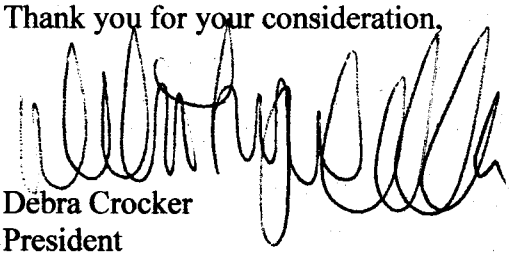
CMS must take these steps to preserve the beneficiaries' convenient access to DMEPOS supplies and maintain established provider to patient relationships. I currently provide testing supplies and other items in my practice and without these revisions to the final regulation; I will be unable to continue providing these valuable services to my rural community.

Thank you for your consideration.



Debra Crocker
President
Pharm-A-Save Inc.
Provider Number 0246250002
NABP number 49-15712

166

HEALTH PRO LLC

COMPREHENSIVE LONG-TERM CARE AND PART B SOLUTIONS FOR OVER A DECADE

By express mail

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

We understand that you are considering proposing inserting a competitive process in the delivery of enteral nutrition products in the long term care industry. We have to voice our concern in opposition to this action as it relates particularly to our residents on enteral therapy as this will place our residents and their caregivers into a precarious environment that could place them at more risk than they are already.

1. **Nursing facility patients are more vulnerable and require a higher acuity level of care**. Patients that reside in nursing facilities are more clinically complex with multiple complexities than patients cared for at home. They have established care plans which could be interrupted as a result of competitive bidding. Patient access to quality products and services, like disease-specific enteral nutrition therapy, could be compromised resulting in serious complications and overall increased costs of care.

2. **Competitive bidding has not been successfully tested in skilled nursing facilities**. Enteral products were dropped after the first round of the Polk County demonstration in order to concentrate on non-institutional settings. In a final report it was concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested.

3. **Competitive bidding puts patient safety at risk**. Suppliers of enteral nutrition products and services to nursing home patients are highly specialized. The potential for a facility to lose their choice of a preferred supplier or to have the ability to provide the products on their own puts patient's health and safety at risk.

3959 ELECTRIC ROAD, SUITE 400 • ROANOKE, VIRGINIA 24018
TELEPHONE: 540-777-1011 • FACSIMILE: 540-777-1004
TOLL FREE: 866-281-1044
www.HealthCareLimited.com

We ask that you please reconsider this action in favor of long term care residents who are most vulnerable, and who must be assured of the timely and accurate delivery of products necessary for life, the ones that demand the most care on the most timely basis and their care givers.

Very truly yours,

Donna P. Grayson

167

Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Evergreen Nursing Home. We are located in Evergreen, Alabama. We are a 61 bed skilled nursing facility employing approximately 85 people. We offer Physical, Occupational, and Speech therapy.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Evergreen Nursing Home we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

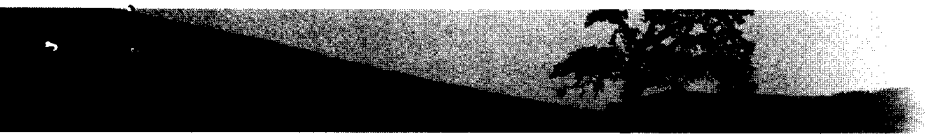
I appreciate your attention to this matter.

Sincerely,

Ann Smith

Ann Smith, R.N., Administrator

Evergreen Nursing Home, LLC • 100 Sanders Drive • Evergeen, Alabama 36401 • (251) 578-3783



amelia nursing & rehabilitation center

Managed by Amelia Life Care, LLC

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

We understand that you are considering proposing inserting a competitive process in the delivery of enteral nutrition products in the long term care industry. We have to voice our concern in opposition to this action as it relates particularly to our residents on enteral therapy as this will place our residents and their caregivers into a precarious environment that could place them at more risk than they are already.

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8830 Virginia Street Amelia, Virginia 23002
(804) 561-5611 (804) 561-5533 Fax www.ameliacare.com

We ask that you please reconsider this action in favor of long term care residents who are most vulnerable, and who must be assured of the timely and accurate delivery of products necessary for life, the ones that demand the most care on the most timely basis and their care givers.

Very truly yours,

Virginia M. Snead

Virginia Snead, Administrator

OXYGENSUPPORTSYSTEMS

(800) 554-1115

P.O. Box 845, Cherry Hill, NJ 08003-0845 www.oxygensupport.com FAX (856) 931-1123

June 28, 2006

Centers for Medicare and Medicaid Services
Attn: CMS-1270-P
Mail Stop C4-26-05 7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sir or Madam,

Please consider the following comments on the Competitive Acquisition for DME to be my concerns about the future quality of the American healthcare system.

As owner of a respiratory company for 27 years I am distressed by the impact of a "winner take all" process on the quality of care now provided to our patients. The proposed change will, over time, erode the high service component of all Home Medical Equipment providers.

Competitive bidding will consolidate the DME industry on the basis of equipment acquisition costs, not on any component of service to the patient. Those companies which remain in business will naturally be the largest companies, who undeniably enjoy economies of scale in the acquisition of equipment. As we must now accept in other industries, customer service for DME will undoubtedly be outsourced or configured to an on-line capability by mega-providers to further reduce costs. Imagine your most senior family member obtaining service for continued use of their medical equipment in this "do it yourself" way. Beneficiaries and their physicians will also face severely limited choice to go to another provider in order to receive improved care and service. Our senior citizens deserve our compassion. We must not make it any more difficult for them to obtain needed service that realistically includes frequent ongoing instruction, on their home medical equipment and it's safe and proper use.

Further proposed rule changes, like the 36-month cap on oxygen equipment, will exacerbate the decline of an industry that is presently very competitive in the quality of care provided. The oxygen cap will reward providers who concentrate on aggressive marketing to obtain new referrals, but who then provide minimal levels of care for each patient because the incentive to provide ever-improving care is gone. Dissatisfied patients who seek better care will find fewer and fewer providers interested in them as the 36th month approaches.

From all reports, the exact savings of competitive acquisition are uncertain. And, in my mind, other cost saving methods have not been adequately explored. Take, for example, Congress' mild interest in enforcing Medicare's existing provision to obtain providers' lowest price for Medicare beneficiaries. News reports stated that the government declared the program unfeasible after receiving "more than 150 letters" from hospitals, drugstores and other providers. Do you think those 150 objections may have come from providers giving large discounts to HMO patients?

153 Harding Avenue, Bellmawr, NJ 08031 (856) 931-1121
22 S. Third Street, Hammonton, NJ 08037 (609) 561-2225
8 Franklin Street, Riverside, NJ 08075 (856) 461-4222
3370 S. Delsea Drive, Vineland, NJ 08360 (856) 765-1000
7317 Oxford Avenue, Phila, PA 19111 (215) 831-8121

All the debates about Medicare cost saving, including competitive acquisition, are being orchestrated by, and will favor, the largest medical providers who have the most to lose if quality of care remains the standard for competition in healthcare. The adoption of these changes will usher in an era of mediocre and impersonal care that American's will rue forever when it finally confronts them in their healthcare.

Very truly yours,

Dana S. Green, President

1170

Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator Crowne Health Care of Eufaula located in Eufaula Alabama And we are a Licensed 180 Bed Skilled Nursing Facility with an Special Alzheimers Unit. We employee 230 people.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care of Eufaula we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Bryan Saylor

Crowne Health Care of Eufaula, LLC • 430 Rivers Avenue • Eufaula, Alabama 36027 • (334) 687-6627

CROWNE MANAGEMENT LLC 401 (K)

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June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Crowne Health Care of Greenville located at 408 Country Club Drive, Greenville, AL 36037. This facility has 118 beds and 150 employees. Crowne Health Care of Greenville offers skilled nursing care along with therapy rehabilitation which includes occupational, speech and physical therapy

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care of Greenville we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Bryan Jones, Administrator

501 WHETSTONE STREET ** MONROEVILLE, AL ** 36460
OFFICE (251) 743-3609 ****** FAX (251) 575-5618

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RESNA

National Office: Suite 1540, 1700 N. Moore Street, Arlington, VA 22209-1903
703/524-6686, Fax: 703/524-6630, TTY: 703/524-6639
Website: www.resna.org

Canadian mailing address: P.O. Box 969, Etobicoke Station U
Etobicoke, Ontario M8Z 5P9, Canada

June 27, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1270-P; Section 2e: "criteria for item selection"

To Whom it May Concern:

The RESNA Standards Committee on Wheelchair and Related Seating submits the following comments regarding the criteria for item selection (section 2e) in CMS-1270-P. In 2003, the majority of wheelchair cushions were classified under the E0192 code. Since the 2003 high volume item analysis, the change in wheelchair cushion coding has resulted in several new codes for these items. The emphasis on performance-based testing for wheelchair cushions has allowed better differentiation of product performance. Cushions in the "skin protection," "positioning," "skin protection and positioning," "adjustable skin protection," and "adjustable skin protection and positioning" categories require a high level of service delivery for proper application.

The broad E0192 code has been segmented into multiple codes. These codes are differentiated by the specific testing criteria based on functional performance. During development of the performance based testing, we have needed to address the myriad of manners in which cushions perform. For example, positioning cushions must address postural alignment, accommodation or correction. Therefore, our testing must allow for cushions to perform in any or all of these manners. Extending our test development into the prescriptive environment, practitioners must also do the same. Practitioners must determine through evaluation the individual's needs and appropriately determine the wheelchair cushion that meets these needs.

A competitive bid product category that reduces the commercial options available restricts the practitioners' range of appropriate options, which results in restricting beneficiary access to appropriate intervention. Cushions in the "general use" classification are the only products suitable for competitive acquisition.

Sincerely,

Patricia E Karg

Patricia Karg, Chair
RESNA Standards Committee on Wheelchair and Related Seating

JOSEPH T. HOGAN, D.P.M.
PODIATRIST

41 Oak Street
Binghamton, N.Y. 13905

(607) 723-7454
Fax (607) 723-1567

502 Fifth Avenue
Owego, N.Y. 13827

(607) 687-5252

DIPLOMATE:
American Board of Podiatric Surgery
American Academy of Pain Management
Amer. Board of Podiatric Orthopedics & Primary Podiatric Medicine
Amer. Board of Quality Assurance & Utilization Review Physicians

FELLOW:
American College of Foot Surgeons
Amer. College of Foot & Ankle Orthopedics & Medicine
Founding Fellow: Amer. Professional Wound Care Assn.
American College of Podiatric Medical Review

Adjunct Clinical Assistant Professor - N.Y. College of Podiatric Medicine
Adjunct Clinical Assistant Professor - Temple University College of Podiatric Medicine
Adjunct Clinical Associate Professor - DesMoines University College of Podiatric Medicine & Surgery

173

June 22, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r).

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Joseph T. Hogan, DPM

Joseph T. Hogan, DPM

West Gate Village, LLC

Mark Manning, Administrator

Telephone (251) 867-6077
100 Pineview & Third - P. O. Box 49
Brewton, Alabama 36427

174

ahca

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at West Gate Village LLC. We are a 129 bed skilled nursing facility in Brewton, Alabama. We utilize therapy services and employee an average of 185 employees.

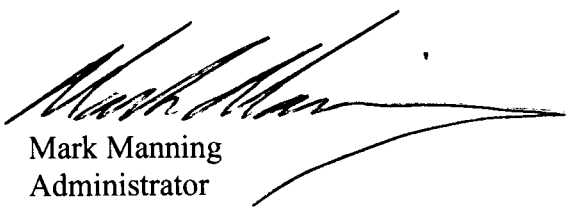
The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At West Gate Village, LLC we have numerous residents whose care could be interrupted as a result of the implementation-jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.



Mark Manning
Administrator

Original

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Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1270-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Comments for Medicare Program Competitive Acquisition
File Code: CMS-1270-P

As a small 20 year businessman, employing 14 people in Augusta, Georgia, I am submitting these comments knowing that my one voice will likely not be adhered to. As an American, the land of opportunity, I know that this is one thing I can do to "hopefully" make a difference.

Having been in this business of home medical equipment for 20 somewhat years, it makes me angry, depressed, and frustrated to see a "not socialized medicine" industry be destroyed by this ridiculous effort to "bid" out health care services and develop a two tier health care system. Two tier for "those that have" and those that "have not."

As everything in government the MMA of 2003, established this program with instructions to see it implemented. And that may be my first objection. Little or none of the details of the program are in place, for this program to take place. So it seems we should look at what was the "objective". If it really is to cut spending, then why not cut spending instead of reorganizing the program. Since 1980, almost 20 years we have developed and streamlined the current program. Each and every year we find ways to cut spending through fee reductions, freezing of CPI, apply inherent reasonableness, etc. etc. So my first point made is: Just cut fees, until providers no longer provide the service. End of conversation. American business philosophy of supply and demand takes over and all money spent on planning, implementation, and administration of all these new programs is saved. Eliminate all these bureaucratic jobs, more money saved.

After reading, hearing, and seeing the NPRM's, first they do not make clear all the things we need to know to react and implement. Secondly, they add more burdensome layers of rules, policies, and regulation that few persons can explain. Having said that I will still attempt to respond to some of the things I feel strongly about.

1. The cost of participate far outweighs the profitability left to the Medicare program. It will drive out or eliminate many or most smaller providers. Any trick to allow "networking" of small providers is not feasible or reasonable.

2. Selection of the ten MSA's has already been biased if the three largest Metropolitans are excluded. Admittingly they will be included later but there

is something wrong with the plan if "anyone" can get themselves excluded. "If it's not good for the "goose" theory!"

3. The law required an oversight committee (PAOC) CMS has explicitly rejected or ignored many of the committee's recommendation. What then was the purpose of this PAOC committee? Doesn't seem the American way that some must follow the rules but not CMS.

4. MSA's not identified. How can a business plan a bid if we don't have the rules? Another obvious attempt or inability for CMS to do there job in a timely fashion. Stop the program until all the rules are written, and thought through.

5. Equipment not identified. If we really thought the program will save money than identify what items the savings are going to be taken from. It is a joke that we should be planning a bid and we don't yet know on what equipment. But don't forget the law says it must meet certain savings but no one can identify from where?

6. Rebates: In the 1980s and 1990s, discussion of rebates was considered illegal or deceptive at best. Providers were threatened with exemption from the program. Now that it is CMS's idea, it is "legal" or a good idea. Fraud and abuse is being suggested and non controllable.

7. If you participate and win the bid, you can't sell your business. These are business rules applied in dictatorships. The American economy is based on free enterprise and supply and demand. Where does our government get off on dictating the free enterprise system? If bidders lose their "business", which in the program will happen, the program will not suffer but the patients and beneficiaries will. This locked in concept will make it again limit fewer companies willing to take the risk and therefore eliminate even more small businesses.

8. Accreditation: In theory, it sounds good, but in reality it is part of the problem. It adds layers and layers of additional costs to any operation and yet the program wants their cake and eat it too. You don't have agencies available to accredit everyone for seven to eight years. So delay the accreditation requirement until you have the agencies available. Or better yet let the patients /beneficiaries dictate the quality or value they get by giving them their choice to deal with their local companies and let competition control the value.

Conclusion:

In general, the entire plan or competitive bidding is bad policy. The reasons are obvious but yet we continue to spend years working on this program and still do not have the rules drawn up. Small business and local providers are being eliminated. Patients, the

Medicare beneficiaries that worked and contributed to the program "were promised reasonable health care." It is their tax dollars that we are "wasting!" Be man enough to admit this bureaucratic mistake and ditch the program. If you can't control your budget and spending, admit it and let's fix it. Quit creating these administrative monster programs that you can't even finalize into a plan. Cut the fees, let the American business philosophy of supply and demand do its job that it has been doing for hundreds of years. Get CMS, the politicians, and any other bureaucrats out of this program and cut the fees. I believe two things will happen. Those that cannot compete on level playing grounds will exit the program. Second, if beneficiaries will continue to have a choice, that choice, that this program is taking away, will deteriorate the quality of their health care. There will be no competition, the quality goes away, the technological advances go away, but the "two tier" health system develops. The health care system for those that "have" and those that "have not."

David J. Petsch
Owner
Petsch Respiratory Services
104 S. Belair Road
Martinez, Ga 30907
Medicare Provider # 1293470001

176

Ankle + Foot Center

Seth J. Okun, D.P.M.
Steven M. Blustein, D.P.M.
Martin Port, D.P.M.
George F. Williams, D.P.M.

Michael A. Fleeter, D.P.M.
Robert E. Creighton, D.P.M.
Juan J. Rivera, D.P.M.
Kenneth Friedman, D.P.M.

Iliya Beylin, D.P.M.
Scott M. LaBohn, D.P.M.
Andrew Saffer, D.P.M.
Amanda M. Bartell, D.P.M.

Tampa
2835 W DeLeon St., Ste. 101
Tampa, FL 33609
(813) 254-4747 / 254-4231

Tampa
13907 N. Dale Mabry
Ste. 103
Tampa, FL 33618
(813) 963-1833

Temple Terrace
6610 Fowler Ave., Ste. D
Tampa, FL 33617
(813) 989-2424

Riverview
7243 Hwy. 301 S.
Riverview, FL 33569
(813) 671-3100

Plant City
1408 W. Reynolds St., Ste. A
Plant City, FL 33566
(813) 754-9876

Brandon
320 Oakfield Dr. #D
Brandon, FL 33511
(813) 571-0123

Apollo Beach
201 Flamingo Drive
Apollo Beach, FL 33572
(813) 641-9305

St. Petersburg
5750 5th Ave. North
St. Petersburg, FL 33710
(727) 384-5540

Clearwater
1700 McMullen Booth Rd.
Ste. A2-2
Clearwater, FL 33759
(727) 725-2719

Zephyrhills
38105 13th Ave.
Zephyrhills, FL 33542
(813) 715-4747

New Port Richey
6331 SR 54
New Port Richey, FL 34653
(727) 845-0880

June 28, 2006

Mark B. McClellan, M.D., PhD.,
Adminstrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS - 1270-P
Mail Stop : C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Dr. McClellan:

My name is Steven M. Blustein and I am a practicing Podiatrist for over 20 years in the state of Florida. I am Board Certified in Foot and Ankle Surgery and have been providing Podiatric, medical and surgical services to patients in the Tampa Bay area for the last two decades.

As a Podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as a daily part of patient care. These individuals are my patients and they rely on my expertise to provide the best medical judgment and skills when treating them. I maintain a valid DMEPOS number, I am subject to the same Stark requirements as MD's and DO's, and adhere to the current supplier standards. As a Podiatric physician, I should be given the same consideration that is given to MD and DO suppliers, including the ability to supply select DMEPOS items to my patients as well as, of course, the right to execute a physician authorization.

I am writing to urge the Centers for Medicare and Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r)(3).

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the Competitive Acquisition Program. I wish to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA), my patients will be negatively impacted.

In my practice I daily see severe fractures, ankle injuries, and complicated ulcers and foot pathologies requiring DMEPOS items to properly treat. I strongly request that you consider this letter and I thank you in advance for your consideration.

I remain respectfully yours,

Steven M. Blustein, D.P.M., D.A.B.P.S., F.A.C.F.S..

SMB/sjr

Enc.

177

BRASSTOWN PROFESSIONAL PHARMACY, INC.
13-A2 MURPHY HWY
BLAIRSVILLE, GA 30512
(706) 745-2303*FAX (706)745-2332

June 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-9
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

To Whom It May Concern:

I appreciate the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

I object to CMS' proposal that would require beneficiaries to obtain replacement supplies of certain items, such as, blood glucose testing supplies. I feel that as a pharmacist, I should be able to offer these supplies to diabetic patients and explain the importance of testing blood sugars, just as it is important for me to explain the importance of their diabetic medications. The beneficiaries should have easy access to the these much needed supplies, and if they are unable to obtain them at the local pharmacy, this might compromise the health outcome of many diabetic patients.

I would like to see CMS take steps to ensure that small suppliers, such as my independent pharmacy/DME business, can participate in the bidding program. Small suppliers should be alowed to designate a smaller market in which to provide DMEPOS . It would be impossible for small suppliers to compete in large metropolitan areas, therefore, small suppliers should be allowed to designate a smaller market to provide DMEPOS.After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment for each item should be allowed to do so.

As much as I am concerned about my business, I must say, that my customers, your beneficiaries, should more importantly have easy access to DME supplies, and to be able to maintain an established provider/patient relationship. Currently, I provide the following types of DME in my practice: wheelchairs, w/c cushions, diabetic shoes, diabetic testing supplies, walkers, crutches, leg braces (knee, ankle), back braces and supports, ostomy products, mastectomy products, and hospital beds. Without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

In conclusion, I urge CMS to revise the regulation to include small suppliers and give them the opportunity to participate in the bidding program, so that we can not only stay in business, but that we might be a help to your beneficiaries, who are in our small town.Thank you for considering my view.

Sincerely,

Amy S Galloway, RPh

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Blairsville, GA 30512
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1 of 1

Proposed Rule - Competitive Bidding NPRM Comments

Scheduled MSA's Competitive Bidding Rollout for 2007

As a small business involved in the Polk County Florida Competitive Bid Demonstration Site, the process was long and cumbersome. If anything was learned from this process, it should be that attempting to roll out all of the top 10 MSA's during 2007, will represent a huge task requiring resources not there and risking the ability for CMS to identify problems that occur during a bidding process. **The NPRM does not have the best interest for small Providers, since their schedule for the rollout will give National Companies the advantage for bidding and prevent small companies from organizing into networks to best qualify for the bidding process**. CMS is also estimating that 50% of the Providers may go out of business. Of course, this number does not include the National Companies. This disadvantage is compounded by the fact that CMS has not published the products that will be included in the bid. Not every Provider will have all of the products and services ready to roll out with such a short time frame.

Only Accredited Providers Are Eligible To Submit Bids.

We support this criteria, since we have been Accredited since 1993 and foresee many fraudulent companies falling out of the system. However, there needs to be additional time for credible providers to seek accreditation. About 30% of the companies in the country are Accredited. The capacity for Accreditation from the several entities offering Accreditation in the nation will not be able to Accredit all those seeking Accreditation, since it takes well over six months for a Provider to prepare for Accreditation. The timing selected by CMS should not proceed until ample small businesses have been Accredited. CMS should also publish and identify those entities selected for Accreditation well ahead of the RFB. In any case, **CMS should grandfather those of us who are already Accredited**, regardless of what Accrediting Body you are accredited with and allow time for us to analyze the NPRM against the quality standards we now meet. In addition, not all of those Providers Accredited need time to analyze their costs and criteria, since it is a very costly endeavor to be Accredited. **We estimate that our costs to maintain Accreditation Status costs us in excess of $ 50,000.00 a year, between human resources, training, maintaining standards, etc.** This is a great financial burden for a small business. We have endured cuts in allowable, changes in the capped rental, oxygen cap and competitive bidding coming will affect the cost of servicing beneficiaries and should be considered an integral part of the bidding process. To provide time for winning bidders to acquire accreditation will not provide for the fallout of fraudulent companies out of the system and may result in the fallout of winning bidders, thus creating chaos in coverage and patient service.

Competitive Bidding Process

CMS needs to set up some criteria for Lowball bids, since the bidders are assuming they will receive an amount higher than they bid, based on the pivotal bid principle. CMS will need to clarify this process better. Bids should not be disqualified nor should the lowest bid be the scenario for the winning bid. CMS should consider that some of the Southern States increase in business during the winter months, due to patient influx for just a few months. To select products for the competitive bid based on submitted claims is erroneous, since many of the equipment categories listed in the top 20 group, increase by 30% during the winter months which are December thru March. Utilization changes with patients in and out of HMO's also add to this census.. The process CMS proposes to use, in order to meet projected demand per MSA and measure supplier capacity are not in favor of the small business concern. It favors the National Companies who are high volume regional suppliers. The NPRM fails to mention the % of small businesses or small business networks that will be considered for winning bidders and it fails to mention what safety measures are included to guarantee a

balanced award of the bids. **There is 83% medium to small business Providers as compared to National Companies. The winning bidders should fairly represent those quantities or percentages when awarding the bid in order for it to be fair and equitable.**

Concentrators are at the top of the 20-product category mentioned in the NPRM. What role does the portable system with unlimited refills play in this bid process? Patients are supplied with multiple cylinders to help reduce delivery expenses. Will these cylinders be included in the cap? CMS needs to weigh the negative impact the NPRM will have with the portable system and more so with small DME businesses and on the competitiveness of the second and third rounds of competitive bidding. Small businesses awarded the bid will have to invest in inventory for the first round. What cushions will exist during the second and third rounds for those small businesses that made their investment during the initial round, if they do not participate in the subsequent rounds.

Only companies presently servicing patients in the MSA area selected for CB should be entitled to bid. No company outside these areas, not servicing the specific MSA should be entitled to come in and Bid. Providers established in the specific MSA area for no less than 1-2 years, should be the only ones eligible to bid.

Finally, over the years, a number of companies, both small business and national companies have been investigated, have been found to have either committed fraud, or has had questionable behavior in their billing practices, violation of kickback laws, inducement for referrals, solicitation of patients and have settled with the CMS program for millions of dollars. Yet, these companies continue to participate with Medicare and any company small or large with this history should be denied participation in the bid process. Some of these same companies are members of PAOC board, providing CMS with input for the NPRM.

Competitive & Potential Savings

1) How will CMS determine how many MSA's need to be selected per product category?
2) What supplier capabilities or capacity thresholds will be used to determine the number of Providers or is there a dollar amount that will determine this?
3) What is the financial threshold that CMS will be looking at for establishing Financial Stability. CMS needs to consider that Financial returns have been decaying due to the unending number of allowable reductions, capped equipment, capped maintenance reduction, etc. It is not uncommon for a company to be in the 5-10 % profit margin and still possess Financial Stability. Credit Lines should be taken into account when determining Financial Stabilities and years in business.
4) What are the criteria for determining savings in any of the Equipment Groups. No true analysis was published in the Polk County Demonstration Site. The collapse of businesses, bankruptcies leaving vendors with AR, unemployment benefits, State Aid, Government sponsored training to align the hundreds of employees in new industries, Welfare Aid for employees impacted in areas already saturated with filled jobs and a low unemployment rate. What was the administrative cost of CMS before/during/after? What were the "true" savings?
5) CMS is performing and receiving studies and reports, but there is no indication how much these will weigh in determining it is validity and it is usefulness when performing program savings.

Gap Filling Methodology

We feel CMS should do away with this methodology for setting fees for new DMEPOS, since it will affect or do away with new technology. This provision is totally inappropriate and ineffective. These issues should be addressed via a different process as individual items, based on their individual merits of new technology as it becomes available.

It's my Life's Savings

Do not restrict me from selling my business if I am a winning bid provider. I have worked long and hard, been up many evenings at 2 and 3 AM in the last 32 years to service patients, and used my life's earnings to support my business. Do not place restrictions on what is personal property. True, many companies were bought out after the Polk County Demonstration Site, which resulted in one National Company owing almost 80 % of the oxygen business in that county. Place a cap on how much another company can purchase instead, to maintain the competitive balance. Do not restrict me from selling my business if I am NOT a CB, since I may need to salvage some of my investment, if getting out of the business is inevitable without CMS. Do not punish me for wanting to retire and/or not be able to do anything with my business

Rebates: Is This The Same As A Kickback?

Since I have been in business, kickbacks have been and are against the law. The NPRM describes the rebate program that "allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary". This is contrary to what CMS has forbidden for years and is contrary to other laws applicable to the Medicare Program. It has forever been an item listed in the Fraud and Abuse Law that any waiver of the patients' co-pay without a hardship is in violation of both the Anti-Kickback and Beneficiary Inducement Statues. This has long been an OIG topic in many Fraud and Abuse advisories or memorandums. There is little or none legal basis under the laws for this program. In my view, a rebate is just another word for kickback. You also request that this information cannot be conveyed to the beneficiary or marketed to the beneficiary, but you make no mention that physicians or referral sources should be excluded as well. If it cannot be marketed to the recipient, it should not be marketed to the referral source as well. Rebates should be completely excluded from the NPRM, since it could open a Pandora box for those providers looking to work the system, cut corners and willing to enter into gray areas.

Networks & Sub-Contractors

The use of subcontractors should not be limited to a Network only that represents a number of small Providers. The NPRM needs to clarify the following:

1) Is the Network Administrator needs to be Accredited?
2) Can the Network Administrator Submit claims and receives payments on behalf of the Providers belonging to the Network?
3) Can a Provider participate in a network for one product category and bid for another product independently?
4) Can a Provider that fails to win a bid, later participate in a Network?
5) What criteria does a Network Administrator need to meet in this Bid Process?
6) 20% maximum of the Medicare Market within a competitive area. Will a National Company that holds more than a 20% market share already is excluded from the bid process. It is not uncommon for any of the National Companies to hold greater than 20% of the Medicare market share in a particular product.
7) Any company winning the Bid should be allowed to subcontract as necessary

Patient Care, New Technology And Quality Of Service

Patient Care, Quality of Life, Quality Service and New Technology is what Medicare patients really want. They also want their Choice of Care and their freedom to choose what is best for their health care. The patient does not care for rebates, nor do they care to have health care choices made for them. Patients are always looking for new technology that will improve their quality of life, slow down there progressive diseases, make them feel better and thus obtain longer life. To simply choose the lowest bidder or a bidder who has only serviced a handful of patients or is a "Jack of All Trades" will not accomplish any of the above

A company that specializes or has a lot of experience in oxygen/respiratory over a company who is big in wheelchairs and has a handful of oxygen patients are not the same and should not be considered equal.

Each company, based on their specialty must be the obvious choice for the patient. How is CMS going to tell the difference when the bids are awarded.? We would never dream of bidding on Electric Mobility Products or TENS devices, since that is not our area of expertise. Under the NPRM, I can bid In addition, sub-contract these items, although I am not an expert in this area. " A Carpenter is a Carpenter and a Plumber is a Plumber.

This process will have an impact in the Quality Care of Patients. It is typical for Governmental Bids to award their bids to the lowest bidder. A good example is the VA, who requires Accreditation, among 20 other stringent requirements. These bids result in companies low balling their bids and the government turning an eye to the other 20 requirements due to the savings. CMS should perform a Patient Satisfaction Survey across the nation in the top ten MSA's to determine what VA & Medicare patients feel of their home care services. We know, for we had a VA contract for 9 years and the horror stories we heard from those patients we were assuming for their care at the time of conversion brought to light the poor service, poor care and prehistoric equipment being used, half of which was not performing to manufacturing specifications. CMS must implement checks and balances to prevent this.

Change of Ownership

"The successor entity agrees to assume all obligations and liabilities borne by the prior contract supplier under the contract". This statement implies that any and all equipment nearing a cap, will be the responsibility of the new Provider. If the equipment cost is $ 500.00 and there are two months left for the equipment to cap, the allowable is $ 50.00, the new Provider will only receive three months of rental and forfeit $ 350.00 on the cost of the equipment?, or carry the warranty on what could be old equipment that has already capped. In another example among many, what happens to overpayments made to the previous supplier. Does the new supplier have to accept liability for these overpayments?, specially if the previous Provider went out of business or sold to another Provider.

Furnishing of Items

"A supplier agrees to furnish items to any Medicare Beneficiary who maintains a permanent residence in, or who visits, the CB are and who requests those items from the supplier" This statement does not mention anything about a MB that has already capped on their equipment through a supplier in their area of residence. A typical example would be a patient that travels for the winter to the south for 2-4 months, their equipment has already capped, their equipment was left at home and we provide this equipment to the patient with the knowledge that we will not be reimbursed or is the patient forced to transport their own concentrator, bed, wheelchair, etc.? Alternatively, will the MB pay 100% of the fees from the Provider in the South? Please, note that many southern states increase their patient census by as much as 30% during the months of November thru March.

New Equipment, Used Equipment, Warranties

This area is very vague. A MB receives a "NEW" piece of equipment that is normally warranted by the manufacturer for 12 months on their original date of service. The CB extends the manufacturer warranties to the patient. When the equipment caps, this warranty is at its end. Does the CB have to provide extended warranties no longer provided by the manufacturer? It is now a used piece of equipment, but it was new when issued to this patient.

A patient qualifies for a Manual Bed, but the CB provides a Semi-Electric bed at no extra cost to the MB or CMS. The CB receives allowable for the Standard bed only. Once the equipment caps, the CB retrieves their Semi Electric bed and provides a standard bed, since that is all CMS paid for?. Up until December 31, 2005, the Semi Electric bed was left due to the Maintenance Program of 2 months billing per year to keep the electric bed working. Under the new guidelines, a manual bed is practically maintenance free as compared to a semi electric bed paid as a manual bed. Will this exchange be allowed, or will the patient just have to do with a manual bed from original service date?

Purchased & Rented Equipment

The criteria for this area are very complicated. After reading it several times, I am still somewhat confused. CMS needs to consider that many DME software programs will need to be revamped in order to accommodate these schedules and electronic transmission, adding additional expenses to small business concerns.

Financial Standards

No Certified Audited Financials should be included. This is an added Financial burden on the small business. Large Public Companies are required to perform these as part of their participation as a Public Company. Small businesses would increase their expenses by $ 3-5,000.00 for this process.

Sufficient Number of Suppliers

In an MSA area where there are over 2,000 oxygen patients and only two companies are selected, only National Companies with their financial resources will prevail. CMS needs to revisit this process to allow small businesses to participate and have an equal level of opportunity for bid participation. What are the criteria ? 500 patients per bidder? 250 per bidder? CMS needs to expand the awards of their bids in those categories that will allow for more winning bidders. At least 2, should be at least 10, so that all can bid and compete on the same level.

The fair way to award the bids could be addressed three ways:

1) Companies interested in participating with the Medicare Program must submit a Bid. Failure to submit a Bid will place you out of the program. Rather than to award winning bids, determine the allowable or pricing by product of the selected bid from the bid results. Allow any and all companies that originally submitted a bid to decide whether they want to participate or not at the selected fees from the bids. If a company selects to participate in a product category, they must provide all of the products that are lumped into that bid. This way, the MSA remains competitive and negative impact on small businesses is diminished. These companies would still have to be or become accredited and meet all of the selected standards.

2) The selection and quantity of bidders selected to participate should be based on Provider experience and length of time in providing that product or service. A Provider providing oxygen for ten years and experience in handling hundreds of patients on oxygen should prevail over a Provider with one year experience and just a small handful of Oxygen patients. For example: If an MSA has 50-60-70- 80 %, etc. of oxygen patients or any other product category listed on the bid being serviced by small businesses, the awarding of the bids should provide for 50-60-70-80% of the companies selected to be small business, as compared to National Companies. This would allow for a fair distribution of the Bids between small and national companies. Please, note that many of the National Companies already own a percentage of the market that exceeds your criteria. **CMS should research what market share each bidder already has by product category and disqualify any from the bid in that particular MSA, if that bidder already exceeds or could exceed the market share allowed by the Competitive Bid.**

3) Most Government bids,(i.e. Veterans Administration, Medical Supplies bids, nursing, etc.) have clauses that guarantee percentages of the bid award to small business concerns, veteran owned, disabled owned, minority owned, women owned, as long as their bids fall within the parameter the bidding agency is looking for as part of the bid. This would provide a degree of guaranteed participation for small businesses, which drive the economy, are more prong to provide higher caliber of services and products in order to fulfill the bid requirements. Not that larger companies would not, but there is a tendency to focus more on higher profit margins with large companies as compared to small businesses , since large companies owe their shareholders dividends.

Re-competing Competitive Bidding Contracts.

Unless the bid process is made more small business favorable, we foresee that small businesses will not be around for the second phase. The 37% CMS of businesses is estimating that will not receive contracted status, will damage the competitive edge during the next two rounds. Further, if there is no limit placed on the large National Companies to purchase small winning bidders or keep these companies within a percentage of the share of market, CMS will have the same issue as it now exists in Polk County. This county has one company that holds more than 70% of the Medicare oxygen market, never participated in the bidding process, will offer minimal sources to bid, unless they are national entities, rather than small businesses.

Breach of Contract

CMS must re-structure their method for on-site inspections, since in the past many Provider Numbers have been revoked due to factual errors. The contracted on-site inspectors are in many cases neither inefficient, nor observant enough and their reports are submitted with erroneous adverse findings. This could result in financial hardship to the CB.

MSA Areas Listed in the NPRM

Several of the MSA areas listed in the NPRM include multiple counties. These have been combined in order to make it a top 25 MSA location and in some cases between the top 10 MSA's. A good example is Tampa, St. Petersburg and Clearwater. There is no indication about the adjacent cities that surround these. Is a Clearwater City address the only area that will be in the bid or will the adjacent cities such as Oldsmar, Madeira Beach, Indian Rocks Beach, etc., be included in the Clearwater MSA. The same stands for Tampa and St. Petersburg with dozens of adjacent communities as well that are not listed in the MSA. Further, each of these counties has Providers that do not cross the county lines. The demonstration site included all of Polk County, but for purposes of this Bid, they are lumping counties, without much consideration to those communities, cities and towns that have different names within the MSA.

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AMERICAN ACADEMY OF OPHTHALMOLOGY
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FEDERAL AFFAIRS DEPARTMENT

June 28, 2006

via Express Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8013

RE: Low Vision Eyeglass Exclusion (414.15)

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the proposed for Low Vision Device Exclusion under the Medicare Program. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule.

CMS has proposed the adoption of a definition of "Eyeglasses" under The Social Security Act that is not reasonable and conflicts with Congressional intent.The definition of "eyeglasses" proposed by CMS fails to make the distinction that Congress made between lenses that correct refractive errors in eyes with normal visual function and lenses and devices that enlarge images to make them visible to eyes with subnormal visual function.

The Academy appreciates the need for fiscal responsibility in the administration of Medicare policy and is not requesting coverage of routine eyeglasses or spectacles for Medicare beneficiaries (related to refractive error only). We would like to work with CMS and others to define/develop appropriate coverage/policy for low vision devices/systems that should be part of the vision rehabilitation process. CMS must make a distinction between conventional spectacles and low vision devices.

Eyeglasses Exclusion from the Act

In the Social Security Act 1395y; 1862(a)(7) Congress states:
"Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services -
"where such expenses are for routine physical check-ups, eyeglasses (other than eyewear described in section 1861(s)(8) of this title) or eye examinations for the purpose of prescribing, fitting or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes."

Conversely, the eyewear described in section 1395x; 1861(s)(8) are:
"prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens."

Accordingly, one pair of conventional eyeglasses or contact lenses may be furnished subsequent to each cataract surgery with insertion of an intraocular lens. When used for this purpose, eyeglasses are deemed by Congress to be prosthetic devices replacing all or part of the eye.

CMS's Proposed Meaning of "Eyeglasses"

CMS maintains that the usage of the term "eyeglasses" in the Act is ambiguous and proposes to adopt the following meaning of "eyeglasses":
"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision."

CMS should adopt a meaning of "eyeglasses" that is reasonable and ordinary, as recently held by the United States Supreme Court:
"Where a statute's plain terms admit of two or more reasonable ordinary usages, the Commission's choice of one of them is entitled to deference. See, e.g., Verizon Communications Inc. V. FCC., 535 U.S. 467, 498, 122 S.CT. 1646, 152 L. Ed.2d 701." National Cable v. Brand X Internet, 125 S.Ct. 2688, 2691 (2005).

CMS' choice of the meaning of "eyeglasses" is neither reasonable nor ordinary and not supported by three medical dictionaries:

1. Dorland's Illustrated Medical Dictionary (28th Ed. 1994)
2. Taber's Cyclopedic Medical Dictionary (20th Ed. date)
3. Stedman's Medical Dictionary (27th Ed, date)

The definition of "eyeglasses" in all three dictionaries limits the term to a lens that *increases the visual acuity of the human eye (Dorland's), corrects a defect in visual acuity (Taber's) or corrects refractive errors (Stedman's).* The definitions do not broadly include all devices "to aid vision or provide magnification of images". There is a clear medical distinction between devices that improve visual acuity of the human eye by adjusting the abnormal focus and those that magnify an object for use by the patient with visual disability. Visual acuity can only be improved by a lens made specifically for the individual eye according to a prescription that is derived by refraction of that eye. The lens may be placed in a frame as in spectacles, or the lens may sit directly on the eye as a contact lenses. Those lenses, either in conventional eyeglasses or contact lenses, focus the light from objects directly on the retina of the individual eye. On the other hand, lenses that magnify the appearance of objects and lenses in a camera, such as used in a CCTV, are not individualized to correct the refractive error of the eye and thus they cannot and do not alter the visual acuity of the eye. As a result, they should not fall within the eyeglasses exclusion.

CMS bases its choice of the meaning of "eyeglasses" upon the definition of the term contained in Dorland's, *"a lens for aiding sight"*, but mistakenly interprets Dorland's meaning. The scope of the term is controlled by Dorland's definition of the word "lens": *" a piece of glass or other transparent substance so shaped as to converge or scatter the rays of light, especially the glass used in appropriate frames or other instruments to increase the visual acuity of the human eye."* In turn, Dorland's defines "visual acuity" as: *The ability to discriminate visually between forms, measured by Snellen's test type or, sometimes, by Landolt's rings.*

The definition of eyeglass contained in Taber's Medical Dictionary tracks Dorland's: *"A glass lens used to correct a defect in visual acuity.* Stedman's Dictionary is narrower in scope and equates eyeglasses to spectacles that sit on the nose. The commonality of definitions among the three dictionaries lies in the

improvement of visual acuity, by correcting refractive errors of the eye. CMS should choose among these three definitions in adopting a reasonable and ordinary meaning to interpret the intent of Congress in excluding eyeglasses from Medicare payments, but it does not propose to do so. Instead it devises a new meaning of the term that causes all visual aids to be excluded from Medicare coverage.

CMS can take no comfort in the holding by the United States Court of Appeals for the 1st Circuit in Warder v Shalala, 149 F.3d 73 (1998) *"that the Secretary has the discretion to interpret the statute and to assign a product to a particular Medicare category even when this will result in non-coverage determinations by Medicare"*. CMS maintains that this statement supports its proposed exclusion of *"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision."* We disagree noting that the holding in Warder v. Shalala is controlled by the United States Supreme Court's ruling in National Cable v. Brand X Internet requiring that CMS interpret the Social Security Act using the reasonable and ordinary meaning of terms contained in the Act.

Exception to the Eyeglasses Exclusion

Because the Act contains the term "conventional eyeglasses", CMS argues that eyeglasses must have been intended by Congress to broadly mean *"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision"*. The term, eyeglasses as understood in its reasonable and ordinary sense, includes two subcategories: conventional eyeglasses and contact lenses. Conventional eyeglasses are spectacles - a frame that sits on the nose and contains lenses that correct the refractive error of each eye. Contact lenses are lenses that sit directly on each eye and correct the refractive error of that eye. The function of spectacle lenses and contact lenses is identical. The prescription for both is derived from the same refraction, corrects the same refractive error, and thereby increases visual acuity. Congress deemed conventional eyeglasses and contact lenses provided after cataract surgery as prosthetic eyeglasses, since they provided a replacement for a missing or defective part of the eye. This is consistent with CMS's exclusion from reimbursement of refractive surgery, which also corrects the eye's refractive error.

Congress made an exception to the eyeglasses exclusion for conventional contact lenses after cataract surgery. In section 1862 (a) (7) of the Act CMS argues *that "by applying the eyeglass exclusion to contact lenses, the statute reinforces the interpretation that the use of lenses to aid impaired vision is the scope of what is excluded by the eyeglass exclusion and not just lenses supported by frames that pass around the nose and ears."*
The contact lens used in this situation is to correct refractive error and not all types of visual impairment. There is no evidence of Congressional intent to limit the exclusion to spectacles only; rather, the Congressional intent was to limit the exclusion to lenses that correct refractive error.

The reasonable ordinary usage of the term eyeglass, as described above, is a glass that corrects the refractive error of the eye and improves visual acuity.

Contextual Interpretation of the Eyeglasses Exclusion

CMS' proposed definition of eyeglasses disregards the context of section 1862(a)(7) of the Act. This was aptly stated by the court in Currier v. Thompson, 369 F.Supp.2d 65, 72 (D. Me. 2005):

"The text of the original statute, when combined with the legislative history, casts new light on section 1862(a)(7), at least as first enacted. Subparagraph 7 was clearly directed to annual and routine medical matters, such as physicals, periodic hearing aid checkups, and immunizations. The portion of the subsection addressing eyeglasses is consistent with this underlying intent. Further, the absence of the

later parenthetical language on eyewear highlights the fact that there is no comma between "eyeglasses" and "eye examinations for the purpose of prescribing, fitting, or changing eyeglasses." This juxtaposition encourages the conclusion that, as first enacted, Congress used the term eyeglasses in tandem with its exclusion of payment for 'prescribing, fitting, or changing.' In other words, Medicare would pay neither for glasses nor the examination that prescribed, fitted or changed them. Also, the absence of the term 'eyewear' makes it less likely that Congress, as urged by the Secretary, distinguished between eyeglasses in the more general sense and eyewear. Finally, the statutory language jibes with quoted legislative history, which addressed the eyeglasses exclusion in the same context as a routine physical and distinguished more elaborate treatment, such as those involving cataracts.

Assuming the statutory language as originally enacted would include eyeglasses that are worn, but not lenses that are not, the next question is whether the subsequent amendments of section 1395y(a)(7) alter the original meaning. This subsection was first amended in 1968 when the phrase, 'procedures performed (during the course of an eye examination) to determine the refractive state of the eyes,' was added. Pub. L. No. 90-248, Section 128. In 1990, the parenthetical phrase 'other than eyewear described in section 1395x(s)(8)' was added. Pub. L. No. 101-508, section 4153(b)(2)(B). This Court could locate no legislative history to explain either amendment. However, the text of each amendment suggests neither was intended to achieve a wholesale revision of the subsection; each amendment only tweaked the exclusion to respond to developments."

The Process of Vision: Visual Function versus Functional Vision

The process of vision has several stages: focusing of the image onto the retina, followed by image capture by the retina, and subsequent transmission to the brain, where it gives rise to visual perception.

When the first stage is defective, the retinal image is blurred, preventing the detection of fine detail and resulting in reduced visual acuity. When the cause is a refractive error (myopia, hyperopia, astigmatism, presbyopia) the blurred image can be sharpened with conventional correction (eyeglasses, contact lenses). Such lenses sharpen the image, but do not change its size (visual angle).

When the second stage is defective, the retina cannot capture and transfer a clear or complete image, no matter how well focused it is. The only solution to this functional deficit is to increase the actual or apparent size of the object, which consequently changes the size of the retinal image. Magnification can be achieved by a variety of means, including by:

1. Bringing the object of regard closer.
2. Providing larger objects, such as large print books or notes written with a broad tipped pen.
3. Providing a magnified image of the object, such as on the screen of a video-magnifier (CCTV). Note that the camera built into the video magnifier includes a lens; this lens, however, produces a minified image on the image sensor. The magnification of the screen image is produced entirely by electronic means.
4. Making objects appear larger through the use of lenses or sometimes mirrors. These lenses do not affect the sharpness of the retinal image, but only its size. Since these lenses affect a quality of the object, they need to be in a position that is fixed relative to the object (at their focal distance). In hand magnifiers the lens-to-object distance must be maintained by the user; in stand-magnifiers it is maintained by the stand. As long as the appropriate lens-to-object distance is maintained, the eye-to-lens distance can be variable; the lens-object combination can be held away from the eye or close to it.

Devices Outside the Eyeglass Exclusion

An eye whose subnormal visual acuity is not caused by a refractive error and therefore cannot be restored to normal visual acuity by correcting the refractive error with eyeglasses – spectacle or contact lenses – is in a pathological state with a permanent visual impairment caused by disease, injury, or congenital defect. CMS recognizes visual impairment as a pathological state qualifying for rehabilitation training by occupational therapists when the visual impairment results in a functional deficit. CMS recognizes visual impairment to include best corrected visual acuity ≤20/70, or central scotoma, or visual field deficit. Rehabilitation therapy to enable the patient to perform necessary activities of daily living in spite of visual impairment often includes, but is not limited to, the application of magnification devices to the performance of these activities. These devices do not correct the visual acuity through the correction of refractive errors; they are prosthetics that replace part of the function of a non-functioning organ.

When used by individuals with a permanent moderate, severe or profound visual impairment, hand, stand, and head-mounted magnifiers and portable CCTVs may be considered prosthetic devices, just as eyeglasses are prosthetic devices when used by individuals who have had their lens removed by cataract surgery. Alternatively they may be considered orthotic devices in that they replace or improve the function of a malfunctioning body part or organ.

Medicare Part B will reimburse patients for expenses incurred for items or services *provided they are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member*." 42 U.S.C. Sections 1395k(a), 1395y(a)(1)(A); 42 C.F.R Sections 411.15(k). Reimbursable items include *durable medical equipment which is used in the patient's home.* 42 U.S.C. Section 1395x(n), 1395x(s)(6); 42 C.F.R. Section 410.38. As per C.F.R. Section 414.202, an item qualifies as durable medical equipment (DME) if it:

1. *Can withstand repeated use*
2. *Is primarily and customarily used to serve a medical purpose*
3. *Generally is not useful to an individual in the absence of an illness or injury; and*
4. *Is appropriate for use in the home.*

Stationary CCTVs meet all four of these criteria for durable medical equipment. They certainly withstand repeated use, are not only primarily and customarily used to serve a medical purpose, but are essential to serve a medical purpose for individuals with a severe or profound impairment of visual acuity (≤ 20/200) or with a small island of remaining central vision. They are useful only to individuals with visual impairments, they are not useful for any purpose in individuals with normal visual acuity, and they are appropriate for use in the home. Like hand, stand, and head-mounted magnifiers, they do not correct visual acuity; indeed, the eye does not even look through the camera lens used in the CCTV.

Conclusion

CMS does not have the authority to exclude Medicare payments for *"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision."* Congress intended the eyeglasses exclusion to apply exclusively to lenses that correct refractive errors that thereby increase the visual acuity of the human eye. Only conventional eyeglass lenses and contact lenses appear to fit this description.

The Academy appreciates the opportunity to comment on the proposed rule. CMS should make a distinction between conventional eyeglasses and devices/assistive technology that are part of a comprehensive vision rehabilitation effort and the Academy is willing to contribute to the development of such policy. In the meantime, if there are additional questions and/or comments regarding the cost of ophthalmology code inputs we encourage CMS to contact us. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response to our comments.

Sincerely,

Michael X. Repka, MD
Secretary for Federal Affairs

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VNA Home Health of Maryland

7008 Security Boulevard, Suite 200
Baltimore, Maryland 21244-2504
410-594-2600 1-888-523-5000
www.vnamd.com

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P - Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

June 28, 2006

RE: 1270P – Regulatory Impact Analysis-Effect on Beneficiaries – Sect E. pg.41

To Whom It May Concern:

The VNA Home Health of Maryland is a Home Health Agency that has been servicing the Greater Baltimore Metropolitan area and surrounding counties since 1895. Our agency is multi-disciplined, providing a full complement of skilled home care services.

The professional staff of our agency has followed with great interest the pending CMS Competitive Bidding initiative, and as health care professionals have very real concerns about the efficacy, implementation and ultimate results of the proposal in its current state. Our staff is particularly struck by the apparent lack of consideration of the considerable intensive areas of specialization required to adequately address patient needs.

In creating an atmosphere that rewards the "super store" approach, patients with complex and specialized needs for DME, cannot be serviced adequately, leading to the following adverse results. 1) Lack of adequate accessibility to quality services, especially in the larger Urban Metropolitan areas that have historically been best served by the small local entrepreneur who understands their clientele; are especially understanding of their needs, and can provide services in a timely and convenient manner. 2) The goal of any health care delivery system should be to provide the best possible opportunity for the patient to achieve a quality of life which will allow that patient to assume independent living and to become productive members of society to the greatest extent possible. A system that fails to adequately address the specialized needs of the medically complex patient, is a system that is more concerned with short term savings, at the expense of those patients who are the most vulnerable. 3) The incredible cost of avoidable acute care, necessitated to correct conditions that where allowed to degenerate due to poorly fitted, and inappropriately directed durable medical equipment, which is an absolute consequence of a system that is solely based on the lowest cost, without adequate regard for the complex and specialty needs of the patient.

VNA Home Health of Maryland

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Enclosed please find two letters from our staff, one from and Occupational Therapist, and one from a Registered Nurse, both of whom having had decades of experience in their respective fields, addressing these concerns. We respectively request that these comments be include in the official record, and that CMS take a serious look at the potentially disastrous effects of this initiative, and create a task force with Industry participation, to develop a program which adequately addresses CMS'S concerns of escalating costs, without potentially jeopardizing the welfare of the very beneficiaries they have been mandated to service.

Yours very truly,

Barry M. Ray, CEO
VNA Home Health of Maryland

WinCare

P.O. Box 7276 – Rocky Mount, NC 27804 – (252) 443-2872

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MEMORANDUM

TO: Centers for Medicare and Medicaid Services

FROM: Sarah Drewry, Director of Field Service
Compliance Director

DATE: June 20th, 2006

RE: Concerns with Competitive Bidding

The main goal of a Durable Medical Equipment company is to provide products and to receive reimbursement. The competitive bidding rule will take away the "any willing provider" environment that was established and will focus on the competitive market, where bidding will be required in order to receive reimbursement. When dealing with nursing facilities, patients and families, is this really where our focus needs to be?

There are several points of this rule that concern us as a Durable Medical Equipment company.

- The competitive bidding rule has not been successfully tested in the skilled nursing facility setting. This rule will affect skilled nursing chains throughout the United States. It would seem that there would be a focus on testing in this situation when it will affect so many people.
- Putting the safety of your patients at risk. A provider of enteral nutrition to skilled nursing facilities is a specialized market. When having to sacrifice your "choice" provider, you are putting your patients at risk.
- How can a program be implemented without accreditation guidelines being established? At this time there has been no information released about how companies that are being affected by this rule will become accredited with the program.

The Competitive Bidding rule that is currently in legislation will make this process much more of a competitive market. When dealing with someone's well being, is that really the most important thing that suppliers need to be concerned with?

Thank you for considering our thoughts.

SBD:slp

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WELDON PHARMACY, INC.
1280 HUEYTOWN ROAD
HUEYTOWN, AL 35023
205-4912805

June 15, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Sevices
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re:CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers-this restricts beneficiaries' choice. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies and ostomy and urological supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding to those unique products that could be provided by a central supplier.

I urge CMS to take steps to ensure that small suppliers-which include the majority of pharmacy-based suppliers–can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to compete in large metropolitan areas.

After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.

CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

I currently provide the following types of DMEPOS in my practice diabetic testing supplies, ostomy and urological supplies, nebulizers and inhalation supplies, ambulatory equipment{canes, walkers, crutches}, bedside commodes,and diabetic shoes, and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

In conclusion, I urge CMS to revise the regulation to :

1. Competitive Bidding Areas
2. Criteria for Item Selection
3. Opportunity for Participation by Small Suppliers

Thank you for considering my view.

Sincerely,

Steve Weldon, Rph.
Weldon Pharmacy, Inc.

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Virginia Home Medical

Comments on CMS Competitive Bid Proposal For Home Medical Equipment and Supplies

June 28, 2006
Submitted by Thomas E. Inman II, President
Respiratory Home Care of Virginia Inc., t/a Virginia Home Medical
11842 Canon Boulevard
Newport News, Virginia 23606

Centers for Medicare & Medicaid Services
42 CFR Parts 411, 414, and 424
[CMS-1270-P] RIN 0938-AN14
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Virginia Home Medical has been a Medicare provider for over twenty eight years. Our company's focus is providing respiratory services to patients in there homes or places of residence. In addition, we do supply Home Medical Equipment (HME).

History

Competitive acquisition for HME was engrossed in legislation in the 1980's. Based on the debate offered at the time it was assumed by the industry the driving force behind competitive acquisition by HCFA was because a comparison was made between the different amounts paid by the Veteran's Administration (VA) vs. Medicare for basic DME (hospital beds & mattresses, wheelchairs, walkers, etc.) and home oxygen services.

An analysis of the major differences between these two procurement models is necessary. First, as far as the industry is aware HCFA never conducted an "apples to apples" total cost savings comparison of the VA procurement model and the proposed competitive bid model now under consideration by CMS. The VA system operates more like an "a la carte" menu, whereas, the CMS model has always been an "all you can eat buffet" model. As a previous VA contracted we have first hand experience of the subtle differences and will attempt to outline the major ones below:

► as noted above, the major difference between the two models is the "a la carte" vs. an "all you can eat buffet" comparison. It is best described as a "service" buyer (the VA) compared to a "commodity" buyer (CMS). Based on our specific experience with the VA here is an outline of the major differences between the two procurement models:

• historically the CMS reimbursement methodology for stationary oxygen systems has always been reimbursed utilizing a single modality neutral rate. The VA's "a la carte" model paid a separate rate for tanks, concentrator or liquid systems. Also the VA allowed for the billing of any supply item used in excess of the contract allowance (i.e. cannulas, tubing, face masks, humidifiers, connectors, sterile water, etc.). Additionally, when portable systems were furnished the VA paid for the rental of the portable system and for the contents **of each portable tank consumed** during the rental period. In our experience we routinely received up to $600 per month for portable "contents" on a single patient. Also, when after hours or extra service calls were necessary the VA had a line item in the contract which allowed us to bill them for the service component provided. And finally, we provided monthly respiratory therapist/technician visits which were billed and reimbursed as a separate line item each month.

▶ conducting business with VA required minimal administrative cost. All that was necessary for the delivery, setup and billing for a VA patient was a physician's prescription and a signed delivery/visit ticket from the veteran. Billing was accomplished by submitting a single invoice monthly for all the veterans on the contract. The VA paid 100% of the charges and no expense was incurred trying to collect co-payments from the veteran.

▶ the VA system allows for only one provider to provide services to a limited number of beneficiaries. It is a "winner takes all" model. It should also be noted VA veterans requiring these services are the minority market share in every MSA as compared to the Medicare population. This creates a market segment which providers never consider essential to their survival. Unlike our VA experience the model CMS is proposing affects the majority of our patient base and thus it cannot be viewed, budgeted or bid as a marginal business segment.

Marketplace

It should not go unnoticed the dramatic differences in the HME Medicare marketplace since the idea of competitive acquisition was developed by HCFA. First and foremost as it relates to home oxygen services providers are being paid in the neighborhood of 42% less (not adjusted for inflation) today than back in the 1980's when competitive acquisition was first proposed. Given the compounding affect of increases in labor rates, health and casualty insurance, payroll taxes, accreditation cost, utilities, occupancy cost and fuel for delivery vehicles the average provider's return on investment has dramatically fallen over the past twenty years. Couple this with the ever growing trend of increasing capital requirements to acquire emerging technologies the industry's profit potential has been severely limited if one is to remain competitive in the marketplace.

Simply stated, the marketplace of today does not even resemble the marketplace of the 1980's. For the above stated reasons, and others unmentioned, the evolved procurement system CMS currently utilizes coupled with a very competitive service model employed by the industry provides the government with efficiencies not realized in other government procurement models. The current system is working to the government's advantage.

An example of this is the rapid growth of an expensive oxygen modality being provided to CMS beneficiaries under HCPC codes are transfilling oxygen concentrators. The acquisition cost of these new oxygen concentrators is up to seven times more than a traditional oxygen concentrator. Currently the industry is providing these devices and billing under the current E1390 concentrator code. CMS may not even be aware of the increased cost and benefit to the system associated with this new technology. Additionally there is no way for the provider to recoup their higher cost of providing new technology. There are many more examples where CMS is unable to keep up with emerging technologies with appropriate HCPC billing codes. The dilemma for providers is the question of legal exposure of providing equipment to beneficiaries and not having an appropriate HCPC code to bill under. How will this issue be handled under the competitive acquisition program?

MSA Issues

It is obvious to the marketplace that competitive acquisition will create a two tiered delivery system for CMS beneficiaries. The obvious cause of this dichotomy is the creation of a two tiered pricing system. Providers in MSA's coming under the competitive acquisition program will by definition receive less reimbursement than those providers outside said MSA. Any marketplace analysis will clearly reveal a provider receiving more reimbursement for the same HCPC will be able to provide a higher level of service and/or better (i.e. more expensive) equipment. Does this not go against the fairness doctrine mandate by Congress to CMS to apply the same standards and quality to all Medicare beneficiaries?

The abstract application of allowing CMS to define the MSA marketplace as it sees fit, as long as the boundaries include contiguous zip codes, is ludicrous. CMS has no relative experience nor published reports that this author is aware of in analyzing the specific factors which define the current geographic marketplace within and surrounding all MSAs for HME products and services. The arbitrary nature of CMS's approach is inappropriate and potentially harmful to Medicare beneficiaries residing on the fringe of every MSA in this country. The potential fallout from CMS's approach here is after competitive acquisition is up and running two Medicare beneficiaries living a block apart will be provided service under two separate market models and reimbursement scenarios. The impact is obvious to all but the uninformed. This author does not believe a two tiered delivery system was every the Congressional intend.

It should not go unnoticed there is a major difference between the legislation creating competitive acquisition for HME and the existing competitive acquisition model currently being employed by CMS in the managed care arena. The facts beg the question (beyond Congressional intent) of why does the current CMS competitive acquisition program for managed care (HMO) services allow the marketplace to utilize the "any willing provider" concept. It seems to have been completely ignored for HME services. If ever there was a major concern in the small business sector of dealing with the federal government this single issue clearly demonstrated there is no concern whatsoever of

"leveling the playing field" to assist the small business segment of the provider community. One must ask why should multi billion dollar corporations be allowed the eminent protection of "any willing provider" in their market segment and an industry consisting of virtually all small businesses be excluded from this practice? One can only hope CMS will realize once competitive acquisition experiences several bid cycles and sees the greatly reduced number of providers it will realize the road for a monopoly or duopoly will have been paved. What then will be the impact on lower prices and higher service? Additionally, it should be understood large national HME companies are not interested in serving small rural marketplaces where patient population is much less dense. What will happen to the fewer small providers in these rural markets outside MSA's if CMS invokes the lower MSA pricing model to them? Does CMS believe the large national companies will flock to the rural marketplace in the event their model creates a vacuum? In the years ahead this single issue holds great risk to Medicare beneficiaries living in very rural areas.

Proposed Bid Regulations

Currently CMS has only provided incomplete information regarding the rules and regulations for competitive acquisition. A whole universe of questions exist due to CMS lacking clarity in there release of proposed regulations in this NPRM. Some vital questions are unable to be asked because the basic outline of a business model cannot be constructed due to CMS completely missing the point of offering up a complete set of regulations before issuing the NPRM. Simply stated CMS released just enough information to confuse the issue and the industry. Instead of doing their homework and thinking the entire competitive acquisition reimbursement model through, CMS offered up an abstract model which has only increased the confusion within the industry. That being said it begs the question of how after two completed competitive bid demonstration projects could CMS not know what their competitive acquisition model should look exactly like?

Numerous issues have been created by CMS's lack of disclosing complete information. The more obvious ones will be outlined below:

► Supplier standards have not been defined by CMS. Based upon the more than 5,500 comments sent to CMS on the draft supplier standards CMS has an obligation to publish the final draft standards for public comment before moving forward with any competitive acquisition program. CMS has created an informational "black hole" by not being responsible to the industry, Medicare beneficiaries and Congress in openly and accurately communicating the exact standards applying to the competitive acquisition program. Anything short of a full disclosure and appropriate period for public comment before the standards are adopted smacks in the face of every PAOC member and what is ultimately the right thing to do.
Additionally, CMS has not accepted any information other than anecdotal comments at the PAOC meetings as to the capacity of the industry's current accrediting bodies to be able to accomplish CMS's requirement of accreditation during the unknown length of the CMS defined "grace" period before a winning bidder will be allowed to participate. Has

the potential impact on access in the MSA's under competitive bid even been considered should the winners not be able to achieve accreditation within this "grace" period? This is another example of a complete absence of planning on CMS's part.

▶ how can CMS expect to receive truly competitive bids when bidders are not allowed to submit bids at a higher rate than CMS currently pays? It was clearly demonstrated in the Polk County, Florida and San Antonio, Texas projects that CMS was paying below the market rate for certain items. Thus when the winning bid was calculated the reimbursement rate went up. If that was the market rate for a product in that specific market how can CMS create a system where beneficiaries will be denied access to products at truly competitive and fair rates?

▶ the issue of the methodology of the bid rate being set by the "pivotal" bid creates more problems than it solves. The "pivotal bid" will not be the rate products are reimbursed at. The reimbursement rate will be set by taking the median of the lowest submitted bid and the "pivotal bid" amount. This concept requires the intelligent bidder to carefully think about the rate he will bid. By definition he must consider there is a significant chance that after the bids are evaluated he may be required to lower his bid even further to be allowed to participate should his bid be above the median rate established by CMS. Additionally, the median rate may not even be equal to an actually submitted bid amount. **In what other approved federal government acquisition program is the fictitious "bid" rate allowed to set a price?**

The logic of this bidding structure begs for an explanation. The affect it will have on bidders is for them to hedge their bids realizing they may have to participate at a lower rate than they bid. The very concept of a truly competitive bid is for the bidder to offer his absolute lowest price. The pivotal/median bid methodology smacks in the face of the intent of a truly competitive bid model. It simply will not work as a bid methodology and produce the desired results.

▶ the proposed requirement for winning bidders to be forced to supply upgraded equipment at the bid price is ludicrous. How stupid does CMS think the professional HME provider is? On one hand CMS states they want the lowest price possible and then turns around and includes a stipulation which makes it **impossible** for anyone to calculate the impact to their bid. If the physician can order an upgraded product and CMS takes the position the upgraded item is included in the bid it will have a devastating impact on the marketplace. An analogous example would be for the DOD to publish a RFB for the rental of vehicles for TDY personnel at bases throughout the continental United States. The example here would be that the rental car agencies would have to submit a per diem rate as their bid, but every base commander could require them to supply anything from a Ford Taurus to an Infinity Q45 sedan. With the inventory to be supplied out of the bidder's control, how can anyone submit an intelligent bid? What CMS needs to do is supply the manufacturer, make and model which will be required to meet the bid for each and every HCPC code contained in the RFB. Anything short of detailing exactly what is included will drastically affect the outcome of the CMS bid process. As noted above, the industry is currently absorbing the higher cost of new technology for which appropriate HCPC billing codes do not exist. Competitive acquisition will destroy the provider/patient relationship by requiring the use of ABN's for newer technologies not

covered by the bid. The point here is, "saying it isn't so" doesn't make it true. CMS has a long way to go before it has any clear understanding of how **competitive** the current marketplace really is.

▶ a parallel to the above topic is the apparent disregard by CMS of how the third party payer system operates in this country. Specifically, providers of products and services in the private health care delivery system are acknowledged as intelligent businessmen by the insurance companies with which they have contracts. To a payer, including HMO's and managed care payers, every insurance company has created a preauthorization/benefit eligibility system where providers are encouraged, and even required in some cases, to determine the insured's eligibility and entitled benefit package **before** the provider provides services. Where does CMS come up with the position that the marketplace will operate in a vacuum created by them concerning Medicare beneficiaries who enjoy limited benefits for the products being bid? CMS's position that the successful bidders must assume **unlimited** liability for providing products to beneficiaries with limited benefits is ludicrous and an insult to anyone with an IQ over 75. Again this is another example of a regulation which makes it impossible for the informed, intelligent bidder to be able to calculate their cost for a product. For the above stated reason CMS has a moral obligation to create a system inclusive of **all** its programs to allow providers **instant** access to the Common Working File to determine both eligibility and benefit dollars remaining by HCPC billing code **before** services are required to be provided. The entire health insurance universe operates using this system. It is simply nonsense for CMS to believe all providers would be financially strong enough to withstand the ever increasing drain on resources created by its requirement to take "all comers" regardless of whether payment would ever occur. The provider is placed in the untenable position of possibly loosing money on every transaction. CMS must rethink its approach regarding bidding requirements for all capped rental items.

▶ the most troubling proposal being offered by CMS is the revocation of a supplier's access to due process. It begs the question, how can a government agency revoke one of the rights any citizen or entity is guaranteed under the constitution? I am not aware of any other government agency which has successfully suspended a contractor's appeal rights. CMS does not have the right to simply **regulate** away the appeal process contained in the Medicare program. It is simply wrong.

▶ CMS's proposal allowing a provider, who's bid falls below the establish reimbursement rate, to rebate some or all of the difference between their bid and the reimbursement rate to the beneficiary boggles the mind of every ethical provider in the country. It smacks in the face of Stark and can only have a detrimental effect on the entire competitive acquisition program. Did CMS ever consult or receive an opinion from the Office of Program Integrity in the Attorney General's office? If so what input did they offer concerning "rebates"? If not consulted, why not?

For over a quarter of a century my experience, as well as the industry's, has been never ending examples from HCFC (CMS), Congress (Stark legislation) and the OIG of demonstrating a "zero" tolerance for "remuneration" in **any** form to occur between a provider and a beneficiary either before or after services are provided.

The proposal offered by CMS will actually create scenarios where a Medicare beneficiary covered by a secondary insurance policy can engage in a CMS rebate program and

actually make money off his rental equipment. This is because his secondary insurance company pays his co-insurance and deductibles. Thus any rebate offered would be money in the beneficiary's pocket. How in good conscience could CMS think a rebate program would ever serve the best interest of the program?
The prohibition on a provider advertising such a program is simply naïve and further demonstrates CMS's complete lack of knowledge on how a competitive marketplace works. The HME referral community is a very small universe and for CMS to believe the "word" would not get out because a provider did not advertise his rebate program is completely naïve. And finally, the mere existence of a potential rebate program will set "heads a spinnin" on how the bid process might be gamed to create a legal kickback program endorsed by the Federal Government. CMS must eliminate any notion of a rebate program and create a system where all winning bidders are on a level playing field if they have any expectation of competitive bidding working over the long run.

► the position that CMS must approve a change in ownership goes way beyond its authority. Should a winning bidder choose to sell his company the only legitimate concern CMS should have is whether or not the new owner can meet the published quality standards. Market capacity is a dynamic concept at best. The ebb and flow of commerce dictates turnover in the inventory of organizations for many reasons. As an example, what if an owner dies in a tragic automobile accident and his estate is forced to sell his company to pay estate taxes. The very act of CMS denying the new owner winning status based on market capacity would so harm the value of the company that it would be tantamount to an illegal taking by the government. This is clearly believed to not be CMS's intend, but serves as just one more example of how poorly thought out most of the proposed regulations contained in this NPRM are.

The above referenced comments are by no means all inclusive to the issues surrounding this NPRM. At best they are an attempt to address the more pragmatic issues which are obvious to this author. Recognizing there are many more legal and procedural issues which need to be addressed I will leave it to the industry attorneys and associations to comment on them far more eloquently than I ever could.

In summary, CMS owes it to every stakeholder affected by this NPRM to withdraw these regulations in total. A complete and thorough reevaluation of the entire Competitive Acquisition program should then be undertaken considering all comments received with new regulations resulting. These new regulations should then be submitted for public comment in the Federal Register.

Respectively submitted,

Thomas E. Inman II
President
Virginia Home Medical

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June 26, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-P
P. O. Box 8013
Baltimore, MD. 21244-8013
<http://www.cms.hhs.gov/eRulemaking>

Re: File Code CMS-1270-P Notice of Proposed Rule Making on Competitive Acquisition

To Whom It May Concern:

Having reviewed the proposed rule making for competitive acquisition, I am confused by several issues which I would like to comment on.

1. It seems a bit like "putting the cart before the horse". National accreditation and previously proposed standard updates need to be established prior to beginning the competitive bidding process. Otherwise bids may be submitted by suppliers who cannot or will not be able to supply beneficiaries with quality products and/or service. The proposed quality standards will affect the cost of servicing beneficiaries, which will thereby, affect the bid itself. To the best of my knowledge not only have the proposed standards not reached final approval, but the accreditation process has not been established. Suppliers do not have a clue at this point in time what procedures will be acceptable by CMS. What establishes a supplier as a "qualified", or "eligible" bidder?

CMS should publish the quality standards in order to facilitate comment on them, before the implementation of such standards on the industry. Previously the proposed standard updates were available for comment, but again I have not seen anything since commenting on them. Accreditation firms, or processes, should be identified and time allowed for businesses to secure accreditation, or at a very minimum be in the process of receiving accreditation. It is my understanding the process can be quite lengthy and costly. For the small durable medical equipment business, I am concerned the research and cost would be prohibitive. However, some standard must be in place prior to soliciting bids to assure the bids made would be cost efficient for the Medicare program and still provide the beneficiary with quality of product and care.

In my opinion the first step should be creating the guidelines which establish a qualified or eligible supplier. This step is the most important. It is the foundation for all other elements of the process. Guidelines need to be created and implemented before the bidding begins to guarantee the continuity of care for Medicare beneficiaries currently receiving items which will come under the bidding process. It also ensures the quality of the bid itself. It would certify the bidding process by assuring only those bidders who can and/or do meet the specific guidelines for operation of their business.

2. "Competitive Bidding" should mean exactly what it says. Bidding should be based an amount the supplier is willing to provide a particular item/service for x number of customers. As I understand it, bids above the current fee schedule would be disqualified. However, some items within the current fee schedule are bare minimum with little or no profit margin for the supplier, especially small business owners who cannot afford to surplus order items. Businesses are expected to show a profit; if they do not show a profit, they will eventually be forced to close their doors.

If CMS received fifty bids for same or similar service, but only needed five contracted suppliers to provide for the beneficiaries within the metropolitan area, would bidder five have the "winning bid"?

What if bidder five's bid was substantially lower than the median of the fifty submitted bids? It appears the payment method would be the median of the contracted suppliers, or in the case of the above example the payment would be the median bid of the five suppliers. And what about the other 45 bidders, are they just out of luck? Will they be forced to eventually close their doors because they cannot accept new beneficiaries for these services? Suppose bidder #30 has several Medicare beneficiaries as customers, will the customers be transferred to another supplier? If so, how does the business make up for that lost revenue? Or what happens when the payment period has reached the maximum for those beneficiaries, but the company could not keep building its business?

Bidding should be truly competitive and affordable for all parties. Additionally, the "winning bid" should be the average bid for the group of products within the particular location. In other words, all bids from the metropolitan area should be taken into consideration and the median of those bids should be the amount of the "winning bid". As this trickles down to smaller cities and towns, the same would hold true. It makes a difference in the cost of service when you have a larger coverage area in terms of mileage. While a metropolitan area might be able to provide the service to its beneficiaries, a rural supplier who may drive 50 or more miles one way to make a delivery or service a beneficiary would have more cost involved for that service, especially when you factor in the rising cost of gasoline.

3. The "Rebate" program which would allow contract suppliers to choose whether to offer a rebate of the difference between their bid and the established payment amount to the beneficiary is also a point of great concern. What if the supplier chose not to rebate the customer? What happens to the additional payment amount then? The contracted supplier would not be allowed to advertise the rebate to potential customers. However, CMS would identify suppliers who offer rebates and the amount of the rebate in the materials it distributes to beneficiaries and referral sources! Isn't that a form of advertisement? Why can CMS advertise the information, but the supplier cannot?

How can this not be considered an inducement or "kickback" to the beneficiary? Kickbacks to physicians, beneficiaries, and other health organizations have always been forbidden! Providing the beneficiary a rebate is contrary to other laws applicable to the Medicare program such as the Anti-Kickback Statute and the Beneficiary Inducement Statute. I would think the rebate is illegal.

It also is opposite to the statutory requirement that beneficiary's incur a 20% co-pay. Rebates are given on automobiles, household items, and even as an incentive for early retirement. However, for the competitive bidding program to work - how could one supplier legally offer a rebate over another supplier? Would this lead to allegations of fraud and abuse from the beneficiary?

4. The process to determine the number of suppliers to meet the projected beneficiary demand in a given metropolitan area are vague, but seem to be weighted in favor or larger, higher volume regional suppliers even though small providers will have the opportunity to participate. Further more there are no guarantees that a small business, or a network of small businesses, will be chosen as the "winning bidders".

Additionally, new business would only be directed to contracted suppliers. I urge CMS to consider the negative impact the proposed competitive bidding process could have on small durable medical equipment companies, or companies specializing in the services they offer.

What happens to our company if a regional supplier receives the "winning bid" for beneficiaries in our local area? What happens to the beneficiary's service should regional care be the method of choice for CMS? How does the small durable medical equipment company stay in business without being able to assist beneficiaries living in the area? I think additional research should be done to ensure stability for the existing suppliers who have and would like to continue to do business with Medicare beneficiaries. Wouldn't this place an undue burden on the small company or specialty store?

5. Once competitive bidding has been implemented, beneficiaries who live in a metropolitan area will only be permitted to obtain supplies/service from contracted suppliers. What happened to the

patient's right of choice in selecting their supplier? And if the beneficiary permanent residence is outside of the metropolitan area but they are visiting, the beneficiary can only receive supplies/service from the contract supplier. What about those persons whose permanent residence is in one state, but the beneficiary spends 3-6 months in another state? How would they receive the supplies or service they need?

6. The proposal also allows for physicians to prescribe a specific brand or type of equipment. This could lead to a demand for premium or brand name items based solely on marketing or advertising. Often the "brand name" product has the same benefit as other products which carry a lesser known brand. Many of us in the durable medical equipment business tend to put quality product above the brand name issue. I know of several manufacturers of walkers, but I carry only two brands because based upon our experience with other brands of walker, the ones we handle hold up better over time. In my opinion the quality of the product (meaning how it lasts with beneficiary's extended use), ease of use for the beneficiary, and meeting the needs of the beneficiary are all more important than the brand name of the product.

The contracted suppliers will not be required to carry all brands/models of equipment, but if a physician orders a specific brand/model the supplier does not handle, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. This seems unnecessary because the statement is already true to basic day to day operations. Most suppliers do not carry all brands or models of any equipment. We select the products we want to carry in our store based upon our knowledge of the product, reliability, cost, etc. And most physicians do not prescribe items based upon brand, instead they use generic names if you will, such as hospital bed or wheelchair. Furthermore, the decision to select a certain product based upon brand name should ultimately be the choice of the beneficiary. He/she currently has the right to choose where they fill a prescription for any item the physician orders. If one supplier doesn't carry a particular brand, they may take the prescription to another supplier.

7. In addition to these specific quandaries, I have reasonable doubt left by the undefined MSA. What metropolitan areas will be the beginning of the competitive bidding process? To my knowledge a general list has been circulated which names various cities where the process could start, but nothing has been decided. I think CMS should be required to disclose the specific geographic areas as well as products that will be selected in the bidding process.

The issue of competitive bidding in my mind is a bit ridiculous to start with. The fee schedule sets a limit of what will be reimbursed for a given item or service. These fees are routinely update and/or reduced as is deemed necessary by CMS. Hence, one wonders why have competitive bidding, when there are already boundaries established regarding what charges will be allowed as "customary fee for service"?

Home care is the most cost-effective setting for healthcare. A simple fact amply documented and proven in medical research. It is much less expensive than care in the hospital, nursing home, or assisted living facility. Moreover, spending for home care represents a very modest portion of the Medicare budget. Demand for home care has and will continue to increase for several years along with the medical needs of a growing population of older Americans. The "baby boomer" generation has only begun to reach the age of a Medicare recipient. Spending for home care is clearly not the problem with Medicare. In fact, it's part of the solution! For these reasons, I encourage you to make wise and sound decisions regarding the implementation of competitive bidding for durable medical equipment.

Sincerely,
Ronnie & Teresa Grimsley

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Advanced MEDICAL CONCEPTS INC.
The Prescribed Fit

www.amcbaltimore.com

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATT: CMS-1270-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244

June 29, 2006

RE: 1270 P- Comments related to specific elements of the proposed regulation.
A) Competitive Bidding Areas - Pg. 13 B) Criteria for Item Selection – Pg. 17
C) Opportunity for participation for small suppliers. - Pg. 30

To Whom It May Concern:

Advanced Medical Concepts, Inc. is a durable medical equipment (DME) company specializing in mobility, seating and positioning, for those patients with complex medical needs. Located in Owings Mills, Maryland, Advanced Medical Concepts has served clients in Maryland for over fifteen years. A distinct and recognized strength of the company is the use of physical and occupational therapists as field sales representatives thereby giving the customer a clinical and professional interaction

A) Competitive Bidding Areas – Pg. 13

It was indicated in the proposed regulations, that this program would be implemented in the 10 largest markets initially. Arbitrarily, this was amended to exclude the three largest markets, Chicago, Los Angeles and New York. The adverse effect of this arbitrary decision is to have those providers who otherwise would have been excluded from implementation in the initial phase, suddenly do to no change in demographics, but just because the three largest markets create a challenge to CMS and implementation , that they would now 'move up the list' and have to be included. This is patently unfair. Firstly, if the program works, it should be implemented as mandated, including the ten (10) largest markets with no 'carve out' . Secondly, if the three largest markets create a delay that might be considered unreasonable, than the initial phase should be amended to begin implementation in the next seven (7) largest markets. This would insure that no provider is suddenly penalized, and included in the first phase, who would have otherwise been excluded but for CMS'S inability to devise an adequate system to address the needs of the three (3) largest markets.

In a free market system, companies are constantly being bought and sold, and the economic impact of this decision could be devastating to those who relied upon CMS'S representations as to which providers would be included in the initial phase.

B) Criteria for Item Selection – Pg. 17

This aspect of the proposed regulations is particularly disturbing to our industry, our company, especially our patients, and the services we provide. Page 17 indicates that Orthotics is included, but limited to only those that require 'minimal adjustment'. However, after indicating which items will be included and which will not, there is a chart which indicates that Power Wheelchairs is at the top of your list of those items which will be included! I would refer you to the following narrative, which hopefully will convey the incredible time, effort, detailed application and professional knowledge necessary, to properly deliver this service.

Our Rehabilitation Technology Specialists staff of licensed occupational and physical therapists offer expert evaluation, equipment selection, fitting and follow-up. Each of our RTS's has at least achieved a Bachelor of Science Degree, in Occupational Therapy and Medicine, and we have one who has a Masters Degree in Physical Therapy, and all have specialized training in ergonomics and kinesiology.

Advanced Medical Concepts focuses on custom manual and powered mobility, home medical equipment, as well as custom seating and positioning for proper fit and function with special emphasis on pediatric, adult and bariatric clients. Using accepted clinical guidelines and a systematic decision-making process, we provide the most suitable equipment for the patient. We create seating and mobility solutions designed to meet the unique needs of each individual.

The Advanced Medical Concepts' RTS (Rehabilitation Technology Specialists) provide assistive/rehabilitation technology in the areas of

- Wheeled mobility
- Seated and Alternative positioning
- Ambulation Assistance
- Activities of Daily Living

9H Gwynns Mill Ct. • Owings Mills, MD 21117 • 410-902-7900 • Fax 410-902-1740

We begin with a thorough patient assessment and evaluation performed by a licensed physical/occupational therapist. This includes medical history, work environment, current medical equipment, and family participation. Follow-up evaluation home visits are included in the process.

The RTS offers consumers product choices and meets basic standards of acceptable practice in the provision of equipment including ordering, assembling, adjusting, delivering and providing on-going individualized support and service. The RTS has specialized knowledge of musculo-skeletal anatomy, abnormal neurodevelopment, neuromuscular abnormalities, biomechanical principles, concepts and applications.

Moreover Advanced Medical Concepts substantiates the recommended durable medical equipment with documentation of the rationale as well as follow-up on the outcome after equipment has been delivered. Accurate information is recorded regarding measurements, wheelchair set-up, method of propulsion, patient objectives (posture/pressure relief/ function) and clinical assessment.

Advanced Medical Concepts' staff of licensed physical and occupational therapists offer patients cost-effective options for commercially available products and fabricated components with input from other health professionals such as physicians, nurses and social workers.

Clinical patient outcomes achieved through proper equipment fitting include:

- Increased functional status
- Increased mobility
- Greater independence
- Prevention of medical complications
- Decreased safety risks

In addition to assessment and provision of specialty seating, the RTS also trains the caregiver in how to help the patient into the chair correctly, how to properly move the chair, and elements of chair maintenance.

Providers that do not specialize in custom rehabilitation equipment including power wheelchairs can do patients an injustice through misapplication of positioning principles and poor product selection.

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We believe that the services that AMC and other similar providers provide to their patients with complex medical needs (not just those patients with MS or Spina Bifida), are incredibly specialized, and as such, must be excluded from this proposed regulation.

Providers that do not specialize in custom rehabilitation equipment, including power wheelchairs, can do their patient a serious injustice, through misapplication of positioning principles and poor product selection. The ultimate cost to correct these misapplications, as well as the potential acute care costs that would be required to attend to the needs of the patients because their condition worsened, would be far greater than any savings. This doesn't begin to factor in the adverse effect on the quality of life of the patient.

C) Opportunity for participation for small suppliers. – Pg. 30

It is clear that in its initial form, this proposal was to have ensured that small suppliers should have the opportunity to be considered for participation. Yet, in CMS'S own regulatory impact analysis, they indicate that 90% of suppliers affected by this regulation will be the small DME suppliers (pg.43)! This analysis is in direct conflict of CMS'S mandate. The lack of appreciation for the value that small DME suppliers provide is unconscionable. The following narrative will explain the value of the small specialized DME provider.

Qualified, small DME providers with credentialed staff offer high quality rehabilitation technology (custom manual wheelchairs, power wheelchairs, specialized walkers) to the consumer with medical and physical disabilities. The Rehabilitation Technology Specialist must establish optimal wheelchair fit without over-correction. The custom chair must address the normalization of muscle tone and inhibition of primitive reflexes often seen in stroke patients. Trunk control, leg length discrepancy and lumbar support must be addressed.

If the elderly patient is frail, they may require a tilt/recline wheelchair to provide position change and adequate pressure relief to prevent decubitus ulcers. Without an expert evaluation by a rehabilitation technology specialist, a typical DME company would provide a standard wheelchair ultimately causing the patient to develop pressure ulcers and remain in bed which leads to more complications of immobility.

Advanced Medical Concepts Rehabilitation Technology Specialists visit the patient in their home setting and assess their postural seating needs. It is not a simple procedure of providing a wheelchair or walker because the physician has ordered it. The physician expects the DME supplier to provide the most appropriate product. Our staff has had to

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point out to a physician that a scooter or power wheelchair is not appropriate for a patient who has cognitive or visual deterioration. This prevents the patient from injuring themselves and others as well as saving thousands of dollars for the payor.

Measurements are taken to determine the width, depth, seat to floor height and back height of a wheelchair and seating components. Our licensed personnel assess the flexibility and movement of the patient's hip, trunk, shoulders, neck, knees, feet, respiratory status, pain control, nutritional status, skin integrity and home environment before recommending the proper equipment.

Fitting a multiple sclerosis patient with a wheeled mobility system illustrates why a specialty provider with licensed clinical staff is required. A large DME supplier provides wheelchairs to this population often with deleterious effects.

Multiple Sclerosis is a progressive neurological disease with an unpredictable course. One of the most difficult assessments is figuring out the length of time the patient will be able to use their rehab equipment. For example if a manual wheelchair is purchased, will the patient be able to use it in six years or will it last less than 12 months? It takes an experienced rehabilitation technology licensed clinician to consider whether the patient may benefit most from a manual chair, powered mobility, powered mobility with a joy-stick, or in cases of advanced disease – a powered wheelchair with an alternative input such as head switches or chin control. The combination of physical and cognitive issues must be weighed to determine the most appropriate, cost-effective product. Advanced Medical Concepts is recognized as a reputable, exceptional provider by the Multiple Sclerosis Society of Maryland. We have a proven track record of meeting the complex seating needs of our MS clientele.

Seating and mobility interventions are very challenging because of the number of physical, functional, socio-economic, and environmental variables that must be taken into account. The "one-size-fits-all" mobility solution offered by large commercial DME suppliers can cause significant decreases in patient function. The freedom of movement made available by specialized DME mobility providers such as Advanced Medical Concepts is key to a patient's function, comfort and activity. It is imperative that the specialty provider survives in order to best match durable medical equipment parameters to the user.

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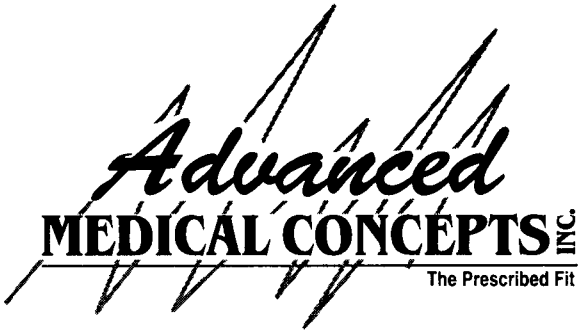

www.amcbaltimore.com

We respectfully request that CMS include these comments in the official record, and that CMS take a critical look at the potentially disastrous effects of this initiative. We recommend that CMS create a task force with Industry participation to develop a program that does not jeopardize the welfare of the very beneficiaries that we are servicing.

Yours very truly,

Ari P. Krupp, CEO
Advanced Medical Concepts, Inc.

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CHAPMAN HEALTHCARE CENTER, INC.
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ALEXANDER CITY, AL 35010
PHONE (256) 234-6366
FAX (256) 234-2366

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the administrator at Chapman Healthcare Center, located in Alexander City, AL. We are licensed for 212 beds. I have 239 employees at the present time. We offer Physical, Occupational, and Speech Therapy at our facility.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Chapman Healthcare Center we have numerous residents whose care could be interrupted as a result of this implementation-jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Archie J. Chapman

Archie J. Chapman Administrator
Chapman Healthcare Center, Inc.

FOX MILL FOOT AND ANKLE CENTER, PLC

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Seth A. Rubenstein, DPM*
George D. Lane, DPM*
E. Kent Picklesimer, DPM

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Reston, VA 20190

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June 28, 2006

Mark B. McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I am writing to voice my opposition to certain provisions of the proposed rule that would establish a competitive acquisition program for durable medical equipment, including prosthetics, orthotics and supplies (DMEPOS).

We currently provide CAM Walkers, night splints and various other DME's through our practice to patients who require such devices. In many cases, DME's are dispensed in an acute setting. This ensures delivery of the best possible care in the most expeditious manner. Most patients, and especially those in the Medicare age group, would not be well served by requiring them to drive from provider to supplier and back and forth again if the device were not fitted properly or needed adjustments.

Physicians represent 3.1% of all allowed dollars for DME. A competitive acquisition program that requires physicians to bid to supply items to patients will likely result in the elimination of most physician suppliers and ultimately result in delayed or diminished clinical outcomes.

I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, form the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of patient care.

Sincerely,

Seth A. Rubenstein, DPM

**Fellow: American College of Foot Surgeons*
**Diplomate: American Board of Podiatric Surgery*

Carolina Foot & Ankle Specialists, PA

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Physicians & Surgeons of the Foot & Ankle

Robert A. Liberatore, D.P.M.

Board Certified: American Board of Podiatric Surgery

Board Certified: American Board of Podiatric Orthopaedics

Fellow: American College of Foot & Ankle Surgeons

Fellow: American College of Foot & Ankle Orthopaedics and Medicine

E. Jason Plumley, D.P.M.

Associate: American College of Foot & Ankle Surgeons

Member: American Podiatric Medical Association

Kristine M. Strauss, D.P.M.

Associate: American College of Foot & Ankle Surgeons

Member: North Carolina Foot & Ankle Society

Member: American Diabetes Association

Specializing In:

Shockwave Therapy for Chronic Heel Pain

Diabetic Foot Care & Wound Management

Reconstructive Foot Surgery

Ingrown & Fungus Nails

Foot & Ankle Injuries

Chronic Foot & Ankle Ailments

Diabetic Shoes, Custom Molded Shoes & Foot Orthotics

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2391 Court Drive
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June 27, 2006

Mark B. McClellan, MD, PhD
Administrator f
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am writing to I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

In my practice I use a variety of DME items. Some common problems I treat include fractures of foot and ankle, tendon injuries, severe foot and ankle deformities. In many cases it is imperative that my patients immediately be dispensed these items from my office. I feel patient care will be compromised if I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide

It is also important to make sure that the devices used fit the patient properly, that the patient understands how and why the device is needed and it is important for them to get the proper device. We are able to stock those devices that work best for my patient population. I fear that if the device is necessary and is not readily available by to the DMEPOS supplier a brand or item of lesser quality will be substituted.

I also employ a Certified Pedorthist and my staff is well trained in the specifics regarding my specialty.

Podiatrists are physicians who treat foot and ankle problems similar to an Orthopaedic surgeon. I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians. Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would not be appropriate to Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,

Robert A. Liberatore, DPM
RAL:bon

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NEIGHBORHOOD Diabetes

Helping To Make A Difference.

Submitter: Thomas Cronin
Title: Chief Executive Officer
Organization: Neighborhood Diabetes
Category: Durable Medical Equipment Supplier
Reference CMS 1270-P
Issue/Areas for Comment: General

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1270-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

To whom it may concern:

Neighborhood Diabetes is a small business with about 50 employees that provides supplies for Self Monitoring of Blood Glucose (SMBG) to approximately 20,000 clients in the Boston area.

The large majority of our clients are covered by Medicare. Unlike other Medicare DME diabetes suppliers whose business model depends on consumer advertising to attract new clients, Neighborhood Diabetes receives its referrals from clinicians, over 1,500 of whom provided us with a referral over the last twelve months. These clinicians vary from nurse practitioners at overwhelmed urban health clinics to endocrinologists at Boston teaching hospitals such as Massachusetts General Hospital.

Our clinicians provide us with referrals because we offer services that help make their patients healthier. These services include: Home visits to new clients to ensure that they are properly trained on their glucose testing equipment in a comfortable environment, home delivery of testing supplies and prescription medications, live people answering the phone, creation of support literature to ensure that common barriers to glucose testing are overcome, and targeted follow-up calls geared toward ensuring not only that clients test their blood sugar, but that they obtain ADA recommended laboratory tests and physician visits as well. We perform these services in the client's native language. Our staff includes native speakers of English, Spanish, Portuguese, Haitian Creole, Khmer and Vietnamese.

Diabetes is different from other conditions because of the chronic nature of the disease, the number of people affected, and the important role that self-care plays in limiting downstream complications. Data

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Wakefield, MA 01880

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clearly shows that better adherence to self-monitoring of blood glucose levels significantly improves quality of life and decreases the cases of complications related to diabetes. In addition to providing our clients with their testing supplies, Neighborhood Diabetes has taken on the responsibility of educating and supporting them in order to achieve better adherence to their testing regimens. Taking this extra step is expensive for us, but it has proven to be a successful educational supplement to what our clients are learning from their clinician. Compared to significant studies, our clients' adherence levels are far better than the average US diabetic population. (For instance, we did a study which found that 74% of our non-insulin dependent Type II diabetics regularly check their blood sugar, as opposed to 39% that were identified in a study[1]of insureds at Kaiser-Permanente of Northern California) .

My concerns with the proposed new rules can be summarized as follows:

Competitive Bidding on diabetes supplies will not save money in the long run:

Implementing a competitive bidding program for diabetes supplies will lead to a 'penny wise and pound foolish' situation. The ripple of short term cost savings from the program will be dwarfed by the tidal wave of costs that will come from diabetic complications suffered by Medicare participants who are not trained sufficiently or face language issues that leave them unable to adhere to their recommended treatment regimen. These complications include very expensive conditions such as heart disease, hypertension, neuropathy, retinopathy, and other conditions. A recent study[2] showed the following:

Average annual healthcare cost for a non-diabetic insured:	$2,560
Average annual healthcare cost for a diabetic insured:	$14,233
Average annual healthcare cost for a diabetic insured with heart disease and an HbA1c > 10.0 :	$46,879
Annual cost blood glucose testing supplies cost (est.)[3]	~$500

Using this data, if the changes caused by Competitive Bidding lead to even a 1% increase in the development of complications such as heart disease among insureds, the cost increase would be $326 per insured (($46,879-$14,233)*.01). This amounts to over sixty percent of the amount paid per year for supplies. Is it possible that being served by the lowest bidder (or a low bidder) as opposed to a company like Neighborhood Diabetes could lead to 1% of the insured population 'veering off track' from their glucose testing regimen and suffering these complications? Based upon our experience we would say "Absolutely". Is there any way that the competitive bidding program will save sixty percent of annual blood glucose testing supply costs? We would say "Absolutely not". Will this program be cash positive for the Medicare program? Again, we would say "Absolutely not".

Competitive Bidding is inequitable to Small Businesses

Clients and health care providers alike agree that Neighborhood Diabetes provides extraordinary service to diabetes patients. With this service level and our additional educational and support efforts, we have consistently helped to make our clients healthier. Our hard work over the years has built a strong business with 20,000 clients. The efforts we have made to build a company based on 'making a difference' to patients should be rewarded, not potentially cast aside by a new set of rules from

Washington.

If competitive bidding in diabetes were to take place in our market, we would essentially lose our entire client base. This is patently unfair to small, regional, single product line companies like ours. Unlike the 'national' companies in our business, we can not bid for contracts in several markets, offering a variety of prices in the hopes of winning some or all of them. To make small firms like ours essentially 'bet the company' on a single bid for our local area puts us at a significant disadvantage to larger concerns. Again, this is just not fair to small businesses.

Competitive Bidding will be bad for Patient Health

As I mentioned in my first point, having potentially low-cost providers offering generic glucose testing equipment and little training or support to patients would actually lead to higher long-term costs for the Medicare Program. This wouldn't just be bad for the program, it would be very bad for the patients covered by Medicare.

In the current reimbursement environment, Medicare suppliers of diabetes testing equipment such as Neighborhood Diabetes compete for clients based on the level of service they provide, rather than price (since the price is set by Medicare). Overall, this leads to better-educated patients, who receive information and training from their suppliers that supplements information received from sometimes overwhelmed clinicians, who face continuously declining reimbursable time with their patients.

To self monitor their blood glucose, seniors who often have difficulty seeing, hearing, or understanding English are being asked to use complex technological devices that are foreign to them. A company that has had to submit a competitive bid will have an incentive to provide the lowest cost product in the most efficient possible manner. We believe this will 'leave behind' Medicare participants who need the type of support or special products we routinely provide. For instance, one of the elements of service that our company takes great pride in is offering a client the glucose monitoring system that best fits the client's needs. We have products that are best for clients with dexterity issues, vision problems, and those for whom 'coding' a glucometer is difficult. In a 'provide a meter at the lowest possible cost' environment, with a limited number of suppliers to turn to, these Medicare patients will have more difficulty getting the meter and training they need to adhere to their treatment regimen, and could develop the terrible complications that diabetes routinely causes, such as heart disease, blindness, foot amputations and the like. The New York Times and other publications have described diabetes as an "epidemic" in the United States today. For CMS to consider instituting a competitive bidding program that could lead to more suffering for the victims of this epidemic, is, I believe, reprehensible.

Footnotes:

1) Karter, AJ et al, *American Journal of Medicine*, Volume 111, July 2001
2) Gilmer, TP et al, *Diabetes Care*, Jan 2005, 28(1): 59-64
3) Neighborhood Diabetes estimate

Following are a few of the testimonials that Neighborhood Diabetes has received concerning its services:

"My staff and I at the Massachusetts General Hospital Healthcare Center in Revere have utilized the programs and services offered by Neighborhood Diabetes. The feedback received from our patients has been extraordinary. My staff has been able to take advantage of a service that is an intangible asset, the home delivery and in-service training. Their unique services allow my staff to spend more quality time with our patients. The courtesy, professionalism, and knowledge of glucose monitors offered by ND gives our staff the utmost confidence in referring our patients to them for diabetic testing supplies.

The customer service exhibited by ND is proof positive that they are truly caring and cognizant of their client's needs. The attention to detail, prompt, accurate, and precise customer service makes ND the most competent diabetes equipment provider. Neither my staff nor I would even think of referring our current or newly diagnosed diabetics to any other company than ND.

Another wonderful feature that my patients have commented on is their ongoing telephone follow-up. This feature allows my patients to troubleshoot their monitor questions and avoid running out of testing supplies. The bottom line is that my patients do not feel 'lost' using ND. There are no voice-recorded messages when calling the office, you get answers immediately and my patients have developed a trust with ND."

Pat Roberge, LPN, *Massachusetts General Hospital - Revere*, Revere, MA

"They (ND) have been exemplary in their care of diabetic patients including in-home training and routine follow up and this has been unmatched by any of our other suppliers. The personal attention that they give patients helps to improve their heath and makes it more efficacious for us to treat patients in an excellent manner."

Dr. Eric Schreiber, Endocrinologist, *Riverside Healthcare Associates*, Medford, MA

"I just wanted to thank you for being so reliable, honest and consistent. I have never gotten one negative report from any of the clients I have referred to your agency. Only the following actual comments from my clients, heard on several occasions:

You get to talk to a real person.

Those boys were so patient with me.

I call them all the time because I forget how to use my machine but they keep helping.

I never run out of test things any more because they call me.

Thank you for making a difference in the lives of elders, and continuing to find new ways to accommodate and serve them as well as you do. Even after your expansion, you managed to offer the same quality customer service and you are setting a fine example for other growing small businesses to live up to. IMPRESSIVE!"

Melissa Manderson, Diabetic Care Case Manager, *SeniorCare, Inc.,* Gloucester, MA

"They (ND) will not only deliver diabetes product supplies in a timely manner but will educate clients on the use of the diabetes related equipment. They will actually visit the home of a client to demonstrate on the use of a meter. . . . It is most refreshing to have a local company, which offers personal care with unprecedented service."

Andrea Penney, RN/CDE, *Joslin Diabetes Center - Anna Jaques Hospital,* Newburyport, MA

"I am writing to sing the praises of Neighborhood Diabetes. They have been wonderful to work with. They are a class act that follows up on their word, a rarity in this present age. Our patients are very grateful for the personal care that they receive from ND, who go to the patient's home and give follow up calls. When we refer to ND I know that the patient will receive excellent care and quality products."

Nancy Perrault, RN,CCM, *South Shore Medical Center,* Norwell, MA

"In my thirty years as a healthcare provider, I can't top the service that this provider has supplied to us and our patients."

Margaret Davis, MS, RD, LDN, FADA, CDE, *Live Nutrition,* Brewster, MA

"I often recommend my clients contact Neighborhood for their diabetes supplies. I have used their services for about two years now and I have no complaints whatsoever about their service. They are responsible, courteous, and best of all, they are the only company I know that sends someone to the client's home to teach them how to use a meter. You can't imagine how valuable a service that is. Not only do they help the client, but they also help the nurses and the diabetes educator in the meter teaching process. As you may know, we have a shortage of time to spend with our clients, and sometimes do a quick review on how to use a meter, or sometimes don't even have time for a review. A quick phone call to Neighborhood enrolling the client with their services and making sure they review the meter usage with the client is a lifesaver."

Virginia Hernandez, RN, BSN, CDE, *Diabetes Management Center,* Dartmouth, MA

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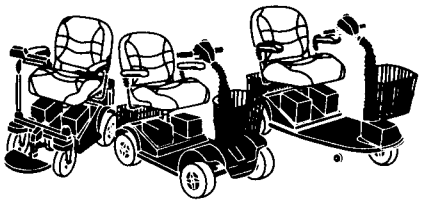

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June 27, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: File Code CMS-1270-P

VIA OVERNIGHT MAIL

Dear Sir or Madam:

Electric Mobility Corporation, DBA "The Rascal™ Company," has reviewed the "Proposed Rule for the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues" and is submitting the following comments pertaining thereto:

Payment Basis (proposed §414.408)

The following citation is of particular concern to our company:

> "We are proposing that if a non contract supplier located in a competitive bidding area furnishes an item included in the competitive bidding program for that area to a beneficiary who maintains a permanent residence in that area, the beneficiary would have no financial liability to the noncontract supplier..."[1]

We believe this provision unfairly restricts Medicare beneficiaries' choices if this applies to cash sales for which a claim would be submitted on a non-assigned

[1] Page 45

basis. Of note, when this question was proposed to representatives of the Centers for Medicare & Medicaid Services (CMS) at the Open Door Forum held in conjunction with the Program Advisory and Oversight Committee (PAOC) meeting on May 23, 2006, those representatives were unable to answer citing that they "hadn't thought of this scenario."

Many beneficiaries prefer the option of choosing a certain type or model of DMEPOS and to bill the Medicare program on a non-assigned basis. To limit, or indeed to eliminate, this option for beneficiaries in competitive bid areas seems an unfair restriction on those beneficiaries' freedom of choice.

Determining Single Payment Amounts for Individual Items: Rebate Program (proposed §414.416[c])

Electric Mobility Corporation is greatly concerned that this program is providing the opportunity for violations of the Antikickback Statute, the Stark Provisions, False Claims Act and runs contrary to the compliance guidance and opinions promulgated by Health and Human Services Office of the Inspector General (OIG). This provision appears to provide the potential for fraud and abuse in an industry that is still reeling from the violations brought to light by "Operation Wheeler Dealer."

Furthermore, the Proposed Rule states "Contract suppliers would also be prohibited from directly or indirectly advertising rebates to beneficiaries, referral sources, or prescribing health care professional."[2] However, at the PAOC meeting held on May 22, 2006, the presentation by representatives from CMS contained the information: "CMS will provide information on the suppliers who decide to offer rebates."[3] While the Proposed Rule clearly delineates that this program is *voluntary*, CMS disseminating information about suppliers who participate in the rebate program creates an unfair marketing advantage to those suppliers.

Terms of Contract: Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding (proposed §414.422 [c])

The following citation is of particular concern to our company:

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[2] Page 102

[3] Page 1 of Presentation entitled "Rebate Program Proposed § 414.416 page 25701." Presented to Program Advisory and Oversight Committee (PAOC), May 22-23, 2006.

> "Repair or replacement of patient-owned DME...that are subject to the competitive bidding program, must be furnished by a contract supplier because only winning suppliers can provide these items in a competitive bidding area. The contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding. This proposed policy will help to ensure that the beneficiaries will get the items from qualified suppliers, and it is consistent with the competitive bidding program in that it directs business to contract suppliers. Therefore, we propose that repair or replacement of patient-owned items subject to competitive bidding must be furnished by a contract supplier."[4]

Given the varying complexity in many areas of DMEPOS, it seems unduly burdensome to expect contract suppliers to service and/or repair patient-owned DME from all manufacturers. How can any supplier be expected to have all replacement parts for all units manufactured in their area of expertise? How can any supplier expect to have staff trained to service all units manufactured in their area of expertise? Rather than affording the benefit of having beneficiaries-owned DME repaired by qualified suppliers, if that supplier does not have the product/part or the knowledge to perform the repair, this will have the opposite of the desired effect. Those beneficiaries may very well receive substandard repairs if the contracted supplier in their area of permanent residence is unfamiliar with their particular piece of DME.

Electric Mobility Corporation appreciates this opportunity to comment on the Proposed Rule and hopes that its observations serve to illustrate our areas of concern.

Sincerely,

Michael Flowers
President

MF:jrb

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[4] Page 105

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SUBMITTED ELECTRONICALLY
AND VIA OVERNIGHT DELIVERY

June 29, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Invacare Corporation (Invacare) is pleased to submit comments on CMS' Notice of Proposed Rulemaking for Competitive Acquisition for Certain DMEPOS and Other Issues. As the global leader in the manufacture of the broadest product offering of innovative home medical equipment (HME) that promotes recovery and active lifestyles, Invacare manufactures and sells to HME (DMEPOS) suppliers a broad array of DMEPOS products, including manual and power wheelchairs, other mobility aides such as canes and crutches; respiratory products such as oxygen concentrators, portable oxygen systems, nebulizer compressors and respiratory disposables; sleep therapy products; home care beds; low air loss therapy products; bath safety products; and patient transport equipment. Much of this equipment falls under the definition of "durable medical equipment" as defined under Part B of the Medicare Program.

Invacare submits the following comments on CMS' Notice of Proposed Rulemaking published May 1, 2006 in the *Federal Register* (71 *Federal Register* 25654), Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. As CMS requested, our comments are divided into sections with "headers" that correspond to the particular subject in the proposed rule.

1. Procedural Issues

A. Need for Additional Comment Period on Issues with No Proposal in NPRM

There are numerous times in the NPRM that CMS provides no specific proposal but instead asks for public comment on a particular issue. For example, under proposed 42

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CFR §414.408(e), "Authority to Adjust Payments in Other Areas," CMS invites comments and recommendations on this issue, without providing any proposed methodology to implement this section of the law. We strongly recommend that once CMS receives comments on this and other issues for which it has no proposal, that CMS issue these proposals in another proposed regulation. If CMS chooses not to do this, there will be absolutely no opportunity for comment on any proposal before CMS issues it in final regulation. This would be wholly inconsistent with the intent and substance of the Administrative Procedures Act. Therefore, we strongly recommend that CMS provide for an additional comment period particularly on issues for which CMS has no identified proposal in this NPRM.

B. Need to Address Competitive Acquisition in conjunction with DRA Issues

CMS' implementation of the DRA provisions on capped rental equipment and the "rent to purchase" of oxygen equipment will have a significant impact on the bid process and bid amounts. These new reimbursement provisions impact winning and losing bidders and beneficiaries. CMS should allow stakeholders to address these issues together when it publishes the DRA NPRM later this year. The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Professional Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

C. Need for Public Comment on Final Quality Standards

Invacare applauds CMS for its apparent intent to ensure that all suppliers providing items and services under the competitive acquisition programs meet defined Quality Standards. At the time of this writing, however, CMS has not issued the final DMEPOS Supplier Quality Standards. We believe that these Quality Standards must be analyzed in the context of this proposed regulation, and therefore ***recommend that CMS either extend the comment deadline for this NPRM to 60 days after CMS issues the final Quality Standards, or allow for a formal comment period on the Quality Standards, for a period of at least 60 days once CMS issues the final Quality Standards.*** In addition, ***CMS should respond to public comments on the Quality Standards as part of its response to comments it receives on this NPRM.***

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CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

At the very least, CMS should schedule a PAOC meeting after it publishes the standards. Invacare strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. Allowing an additional comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental; consequently, CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

D. Need for PAOC Meeting Once CMS Issues Final Rule

Due to the many issues that are not addressed in the NPRM, Invacare strongly recommends that CMS convene a meeting of the PAOC as soon as the final regulation is issued. At this point, CMS must ensure that the geographic locations (MSAs) and products to be included in the competitive bidding programs are known, as well as the detailed implementation schedule.

2. Creditor Issues

According to the CMS Regulatory Impact Analysis, about half of these suppliers will not be selected as contract suppliers, adversely affecting the majority of suppliers in this country. These non-contract suppliers will therefore not likely be able to sustain their businesses based upon the items not included in competitive bidding. We believe the proportion of adversely affected suppliers will be significantly greater for smaller suppliers, given the fact that price will be the key factor in determining which suppliers become contract suppliers.

As the largest worldwide manufacturer of home medical equipment, Invacare extends credit to literally thousands of entities that are Medicare DMEPOS suppliers in the United States. CMS's Regulatory Impact Analysis does not include the costs and impacts on creditors such as Invacare; probably the largest creditor to the HME industry. The stark reality is that competitive bidding will force about half of the current suppliers to go

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out of business. The direct financial impact on Invacare is potentially huge. As a creditor, Invacare has no information to understand which suppliers will be contract suppliers and which will not. As a result, Invacare will be significantly negatively impacted by the implementation of competitive bidding. Invacare strongly recommends that CMS consider and incorporate creditors' impacts in the Regulatory Impact Analysis.

3. Regulatory Impact Analysis

CMS' Regulatory Impact Analysis is, as noted above in the section on Creditor issues, limited in terms of the scope of the real economic impact to the United States. CMS has not considered the larger macroeconomic impacts of forcing half of the DMEPOS suppliers out of business; these impacts include lost jobs, lost personal and corporate taxes, and other direct losses to communities across the country that will result from a large number of small business entities being forced to close their doors.

Further, CMS' Regulatory Impact Analysis overstates the potential savings from implementing competitive bidding. CMS cannot assume that competitive bidding will achieve the same level of savings as were experienced in the demonstration projects in Polk County, FL, and San Antonio, TX. Since those demonstrations occurred, Congress has imposed a series of significant cuts on the major product categories. For example, the Medicare Modernization Act imposed significant cuts to oxygen (11-13%, hospital beds 20%, nebulizers 22%, etc.). Further, there have been CPI freezes imposed on the DMEPOS fee schedules, which are in reality a cut as labor, fuel and other costs have increased dramatically over the last few years. As a result of these series of significant cuts, we strongly recommend that CMS re-calculate the potential savings; and recommend that the Administration request Congress to request that the Congressional Budget Office revise its estimate of savings in light of these facts that will have a direct impact on the potential savings associated with implementing competitive bidding.

Finally, we believe that CMS has significantly under-estimated the administrative costs associated with developing and implementing the competitive bidding program. The administrative costs to review all bidders information to ensure compliance with quality, financial and other standards, physical site visits to potential contract suppliers, bid review, calculation of pivotal bids and single payment amounts, and ongoing oversight in the CBAs will be enormously complex and resource intensive. CMS should re-examine its assumptions, and based upon comments received, recalculate the anticipated costs of administering this program. CMS should then provide that information to the Congress, along with its revised estimate of the potential for savings associated with the program. Looked at together, the administrative costs will not be able to be rationalized, given the meager potential savings that the program might yield.

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4. Need For Product Standards

Without any quality, performance or technical standards in place for all items potentially included in competitive bidding except for power wheelchairs and power-operated vehicle, CMS is creating a program that will result in substantially inferior products. During PAOC meetings, CMS has identified a process whereby it would monitor on a retrospective basis the actual brand items of bid products that are provided to beneficiaries in a CBA. This burdensome process would be administratively impossible to monitor and, CMS has no measures to determine whether the items provided meet any particular standards.

As a way to ensure that beneficiaries are able to continue to receive quality items and related services, Invacare strongly recommends that CMS establish a process for each item subject to competitive bidding that ensures that products that contract suppliers provide are of similar quality compared to products provided in non-bid areas. Specifically, CMS needs to establish quality standards for products as CMS did for power wheelchairs and POVs. Regardless of the level of complexity, there will be durability, performance and other measures to ensure a certain level of product integrity and quality. As CMS did with power wheelchairs and POVs, CMS needs to work with the relevant manufacturers to establish these standards. Once the standards are established, manufacturers would apply for a code verification; the HCPCS code designation would require the product to meet those specific standards. This would ensure that beneficiaries only have access to items of acceptable integrity and quality standards; it would resolve the quality issue at the front end, obviating CMS' need to track from every contract supplier, an itemization of all the products provided to beneficiaries in the CBA.

5. Need for HCPCS Code Refinement

In order for DMEPOS suppliers to submit bids for individual HCPCS codes, there must be a narrow range of technology defined by each HCPCS code. That specificity simply does not exist with the majority of HCPCS codes. We therefore recommend that CMS refine its HCPCS code system for each product category it intends to include in a competitive bidding program. That refinement must be done in consultation with stakeholders, including manufacturers, suppliers, physicians and other clinicians, and consumers, to ensure that HCPCS codes are refined with sufficient specificity. If CMS fails to refine the HCPCS code system for product categories it intends to include in competitive bidding, suppliers will not be able to provide intelligent bid information for each code; because suppliers cannot anticipate the specific future needs of beneficiaries for specific items that will fall with one HCPCS code.

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6. Implementation Contractor

The proposed rule states that CMS will contract with a new entity, the Competitive Bidding Implementation Contractor (CBIC), whose primary functions will be to provide oversight and decision making, operation design functions, bidding and evaluation, access and quality monitoring. There is no further information regarding how CMS plans to choose the CBIC; but Invacare recommends that CMS ensure that any CBIC entity avoids any potential conflict of interest. For example, a conflict of interest would exist if a CBIC were also a private payor that negotiates directly with DME/HME providers in a managed care context.

7. Payment Basis

Payment for Supplies/Accessories for Items Subject to Grandfathering: Invacare supports CMS' proposal that accessories and supplies used in conjunction with an item furnished under the proposed grandfathering process can also be furnished by the grandfathered suppliers.

Payment Adjustment to Account for Inflation (Proposed 414.408(b)): Invacare supports CMS states that suppliers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Suppliers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Authority to Adjust Payments In Other Areas (Proposed 414.408(e)): Effective for items furnished on or after January 1, 2009, CMS has the authority to use payment information from the competitive bidding program to adjust payment amounts to items in an area not in a competitive bid area. CMS is proposing to use this authority, but has not proposed any specific methodology for doing so. Instead, CMS invites comments and recommendations regarding a methodology CMS should use to implement this authority. Invacare recommends that CMS issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

Invacare recommends that CMS use criteria that CMS has established under its inherent reasonableness authority, under section 1842(b)(8) of the Social Security Act, to adjust payment rates for Part B items other than physician services. These criteria are in CMS' final regulation issued December 13, 2005 (70 *Federal Register* 73623). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using

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information derived from competitive bidding, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. CMS should undertake an impact analysis before applying bid rates from a competitive bid area to items in a non-competitive bid area. That analysis should focus on the ability of suppliers to provide the item at that bid rate and the impact on beneficiaries and their ability to access quality items at that bid rate.

We cannot comment further because CMS has not identified a proposed methodology to address in comments. Therefore, CMS should initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

Requirement to Obtain Competitively Bid Items from a Contract Supplier (§414.408(f)):
The NPRM states that if the area that the beneficiary is visiting is not a competitive bidding area, or if the area is a competitive bidding area but the item needed by the beneficiary is not included in the competitive bidding program for that area, the supplier would be paid at the rate of the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposal will make it difficult for traveling beneficiaries to obtain products and services in some areas. While we recognize that this is the current Medicare policy, the maximum payment difference from one state to another is only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. Invacare recommends that CMS continue to pay the fee schedule amount that corresponds with the beneficiary's permanent residence when beneficiary's travel outside their competitive bid area.

There are a significant number of beneficiaries who are "snowbirds", who spend a good portion of the year in a more southern area of the country. This proposed requirement will have a significant and undue impact on suppliers providing items and services to snowbird beneficiaries. It is simply not equitable to impose a bid rate on an item on a supplier in a different area of the country, without any analysis regarding the appropriateness of that new lower price. This proposal will have an undue negative impact on suppliers serving "snowbird" beneficiaries, and CMS should reject this proposal in the final rule. We recommend that CMS modify its claims jurisdiction policy for these beneficiaries because these beneficiaries will likely find it difficult to obtain quality items and services when they are not at their permanent residence. This proposal needs to be changed to ensure that beneficiaries maintain appropriate access to medically necessary items.

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Further, CMS states that it will monitor the programs to ensure that this type of "abuse or circumvention of the competitive bidding process and requirements to obtain items from a contract supplier does not occur." If this "avoidance of competitive bidding contract suppliers" activity does occur, CMS should understand that it is likely a strong indication that the competitive bid program is not meeting physician and beneficiary needs in that area. Beneficiaries would only seek out non-contract suppliers if they, and their referring physicians, are dissatisfied with the quality of items and services available from contract suppliers. This activity should therefore be monitored as a measure of whether contract suppliers are providing beneficiaries with a suitable level of quality and access; there would be nothing nefarious about his activity.

Grandfathering Medicare Advantage Beneficiaries: The NPRM does not address the impact of competitive bidding on Medicare Advantage (MA) patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers: The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS also states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. We appreciate CMS' desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program. We recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of DRA to Oxygen Patients: It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? The implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how

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CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

8. Competitive Bidding Areas

Invacare recommends that CMS identify the initial ten MSAs in the final regulation implementing competitive bidding. The geographic location of the initial ten MSAs is the most critical information that must be made public as soon as possible, to allow suppliers as much time as possible to become accredited and be able to prepare to submit bids.

CMS should stagger the implementation of competitive bidding in the initial ten MSAs to allow for a more orderly roll out of the program. This would also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread or occur in all ten initial MSAs at once.

Establishing the CBAs for 2007 and 2009 (Proposed §414.410(b)): CMS is proposing to establish competitive bidding areas (CBAs) in ten of the largest MSAs in 2007 and 80 MSAs in 2009. However, CMS does not believe it is confined to areas within an MSA, and proposes specific criteria for when to include areas outside an MSA. The statute appears crystal clear that CMS does not in fact have the authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***"in"*** an MSA. Therefore, we strongly oppose any criteria CMS proposes to use to annex areas next to an MSA, and we urge CMS to reject its proposal to have the discretion to define a CBA to be larger than an MSA.

9. Nationwide or Regional Mail Order (proposed §414.410(d)(2))

CMS is proposing to establish a nationwide or regional competitive bidding program, effective January 1, 2010, for the purposes of awarding contracts to suppliers to furnish these items across the nation or a region to beneficiaries who elect to obtain them through the mail order outlet. Invacare recommends that the term "mail order" be replaced with "home delivery," since this more accurately describes the program.

It is unclear why CMS anticipates having a separate CB program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in CA in MSAs during 2007 and 2009, a separate program for them in 2010 would be unnecessary. In addition, many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. A definition of "mail order supplies" needs to be established.

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10. Criteria for Item Selection

Items Included in Competitive Bidding: CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" *as defined under §1834a(13)* for which payment would otherwise be made under §1834(a) *and "supplies used in conjunction with durable medical equipment;"* enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Potential for Savings: CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger CA for a product category?
- *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- *Number of suppliers*: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Regarding CMS' proposed criteria for selecting items to including in competitive bidding, Invacare recommends that CMS add a critical step as it determines which products will be included in competitive bidding. Specifically, CMS should first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category. We find it difficult to fathom that the costs associated with implementing the program would, in many product category cases, make the approach cost effective. Specifically, CMS estimates that its aggregate savings in 2008 will be $110 million. Using CMS' tables for the top ten eligible DME policy group allowed charges, with the allowed charges of $7.4 billion, savings of $110 million indicates a savings of 1.4% in 2008. That seems to be a waste of time and resources,

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including the creation of a new bureaucracy including new Medicare contractors, and other obvious related financial costs. We understand CMS is under a Congressional mandate, however, it would be far more logical for CMS to focus on product categories that will ensure savings that more than balance the associated administrative costs. Therefore, Invacare recommends that CMS first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category.

Definition of "Product Categories": CMS should have included in the proposed regulation a definition of the product categories that it would potentially include in the initial ten MSAs, and we recommend that CMS identify in the final rule the definition of product categories that might be selected for the initial ten MSAs. Further, we strongly recommend that CMS define product categories only as subsets of the current policy groups; CMS should not combine products from more than one policy group. For example, CMS should not include items from oxygen and hospital beds in any definition of "product categories." This will benefit smaller suppliers, and simplify the administration of competitive bidding for suppliers as well as for CMS.

CMS Should Exclude Power Mobility Devices: The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS will lack the cost and volume data required under the formula in the NPRM to select an item. CMS will be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there is not likely to be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding.

CMS Should Exclude High End Custom Manual Wheelchairs: Manual wheelchairs HCPCS codes will soon be the subject of a significant recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchair will probably cost more to bid categorically. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the NPRM proposal, a supplier who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standards, ultra

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lightweight, bariatric or manual tilt-in-space. In many cases, complex Rehab manual wheelchairs require multiple components to achieve appropriate fit and function for the individual. Therefore, due to the complexity of certain manual wheelchair configurations and the new code process for these items, manual wheelchairs will not be suitable for competitive bidding in 2007, and we recommend that CMS exclude these items.

Further, if CMS were to include manual wheelchairs, including high end products, suppliers awarded the contract many not necessarily be awarded the contract for the associated seating items that are used in conjunction with the high end manual wheelchairs. This would lead to unnecessary complexity for consumers, physicians, therapists and suppliers; ultimately impacting beneficiary access to the appropriate items.

11. Submission of Bids Under the Competitive Bidding Program (Proposed §414.412)

Product Categories for Bidding Purposes: Under the proposed rule, each product category would also include all of the ancillary related supplies. Suppliers would be required to submit bids to reflect all items within the product category. We support this approach as it should allow Medicare beneficiaries a "one stop shopping" opportunity to receive all the necessary products and accessories from one contract supplier. Likewise, we support the proposal that would permit a supplier to bid for only the products and accessories they are seeking to furnish under competitive bidding as it permits suppliers to specialize if they so choose.

- CMS needs to be more specific about the information it will give bidders so that they can determine an appropriate bid in light of the requirement that they must accept any beneficiary in the MSA regardless of the number of rental months remaining on capped rental or oxygen equipment.

- Data suppliers will need to have to determine "worst case" scenario – how many beneficiaries using oxygen and capped rental items – that winners may be forced to take on.

12. Conditions for Awarding Contracts (Proposed §414.414)

Quality Standards and Accreditation (Proposed §414.414(c)): CMS is proposing to phase-in the accreditation requirement. Invacare strongly recommends that CMS explicitly require all suppliers submitting bids to demonstrate, as part of the bid submission, that they have already received accreditation status through an accreditation organization that has received "deemed status" from CMS. A "phase-in" approach is inappropriate because it leaves open the possibility that bids from suppliers who may not be successful in receiving accreditation status will be included in the single payment

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amount calculation, and would therefore taint the bid calculation and contract supplier selection processes.

Instead, once CMS announces the initial ten specific MSA geographic locations, CMS should allow sufficient time for all interested bidders to complete the accreditation process (receive notice from the approved accreditation organization that the organization has either met or not the Quality Standards). This would ensure that all suppliers submitting bids have become accredited, and would create a "level playing field" among all submitting bidders in that they have incurred the various costs that accreditation requires.

Therefore, Invacare disagrees with CMS's proposal in the NPRM where CMS states that it will allow a "grace period" during which unaccredited providers can participate in the bidding process. Invacare strongly recommends that CMS not allow unaccredited providers to complete accreditation during an unspecified grace period. If CMS allows unaccredited suppliers to submit bids, then bid information from bidders who do not become accredited during the grace period will be woven into the various calculations – including supplier capacity, pivotal bids and single payment amounts calculations, fundamentally tainting the validity of those calculations. CMS cannot eliminate this deficiency by simply later eliminating those bidders who do not become accredited. Instead of going through the administratively burdensome process of recalculating supplier capacity, pivotal bids, and single payment amounts, it will be far more efficient to allow a defined time period (consult accreditation organizations for what would be the appropriate period of time) to allow suppliers interested in submitting bids to go through the accreditation process.

CMS should allow additional time for suppliers to analyze the CMS final quality standards in conjunction with the NPRM. The quality standards will affect the cost of servicing beneficiaries and as such are an integral part of the bid process.

If CMS chooses to reject this recommendation and allow suppliers a grace period to meet the Quality Standards and obtain accreditation after bid submission, then if one of these suppliers subject to the grace period ends up not becoming accredited, CMS must re-calculate the single payment amount if any supplier is suspended or terminated from the program using the bid amount of the next supplier or suppliers needed to replace the stated capacity of the suspended/terminated supplier.

Finally, CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies.

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Eligibility (Proposed §414.414(b)): Invacare recommends that the proposed eligibility rules be expanded to require that each bidder must provide documentation in its bid submission that it has been accredited by an organization that has received "deemed status" with CMS.

Financial Standards (Proposed §414.414(d)): CMS should consider the following evidence of a supplier's financial stability:

- How long the company has been in business
- Dun and Bradstreet (D&B) report, particularly the paydex score (which measures how quickly the company pays their accounts payable)
- Insurance certificates
- Income/balance sheets
- Cash flow statements (would like to see a pattern of profitability over the last two years)
- Copy of the last two years' corporate tax return statements

Evaluation of Bids (Proposed §414.414(e)): Overall, the bid evaluation and the selection of winning bidders processes should be designed to result in pricing that is rationale and sustainable. CMS has not identified any process in its proposed evaluation of bids procedures that will enable CMS to determine that the submitted bids are rational. Once it receives bids, after CMS arrays suppliers' composite bids from low to high, CMS must conduct an analysis of the composite bids and discard any that are unreasonably low.

Logical Consideration of Criteria: The evaluation of the supplier's financial stability, accreditation status, and compliance with all requirements must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified suppliers should not be considered in selecting the winning bid point or setting the payment amount.

a. Market Demand and Supplier Capacity (Proposed §414.414(e))

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual

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capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

Invacare recommends that CMS use 130% of anticipated Medicare volume as the threshold for the number of suppliers needed in a geographic area. This would promote increased competition in the market, ensure more (smaller) suppliers remain in the market to serve non-Medicare payors and ensure better competition for any future bidding rounds. In addition, this would minimize the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

b. Determine the Pivotal Bid (Proposed §414.414(e))

CMS states that ""During the demonstration, evaluating quality and financial standards was time-consuming for the bid evaluation panel....". This statement implies that CMS does not plan to evaluate the quality and financial standards of all suppliers that submit bids at the outset of the bid evaluation process. We are very disturbed by this implication. *(And CMS should not short-cut the procedures simply because it may be more administratively burdensome – such is the nature of this bidding process.)* Further, it is entirely unclear in the proposed regulation at what point CMS plans to evaluate whether bidders do in fact meet all the requirements, including quality standards (accreditation), financial standards, Medicare supplier standards, etc. It is imperative that CMS conduct this evaluation process at the outset before the bid evaluation process begins to ensure that bid information from a bidder that does not meet one or more of the requirements is

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not included in any part of the evaluation process. Otherwise, the entire bid calculation (including pivotal and single payment amount calculations) and contract supplier selection process will be fundamentally tainted with information from non-qualifying bidders.

c. Assurance of Savings (Proposed §414.414(f))

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations.

Invacare strongly opposes the proposal that suppliers cannot submit a bid that is above the current allowable. Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding areas are expected to be less than the total amounts that would otherwise be paid. To meet this requirement, CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. Invacare strongly disagrees with this proposal because it places artificial constraints on a process that is trying to be designed to harness market forces. If CMS is truly using competitive bidding as a way to understand the price the market will bear, then CMS must allow suppliers to submit their lowest possible bid. Given the many new requirements associated with providing the items and related services under the bid program, bids may rationally and realistically be greater than the current fee schedule amount for the particular item. Given the fact that the majority of suppliers will be incurring new costs of accreditation (compliance with quality standards), and the fact that in the last few years reimbursement has been cut for many of the major product categories (*e.g.*, FEHBP-based reductions), and some products have increased suppliers' documentation costs (e.g., power mobility device documentation requirements), it is highly likely that bids for certain product categories may realistically be at a rate that is higher than the current allowable.

CMS can still meet the "assurance of savings" requirement through alternative means. If bids received are higher than the current allowable, CMS should choose not to include that particular item or product category in the competitive bid program, because that is a strong indicator that savings are unlikely. Requiring that the bid be equal to or less than the fee schedule as a requirement of the RFB artificially restricts bidding. Instead, CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. The "assurance of savings" requirement would be met when CMS only included items for which the winning bid amount were less than the current allowable.

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Selection of New Suppliers After Bidding (Proposed §414.414(h)): CMS proposes to select only as many suppliers as necessary to meet projected demand in a given MSA. However, CMS further suggests that if a supplier falls out of compliance with any of the requirements identified in the regulation and in the bidding contract, it may be necessary to suspend or terminate their contract. This could result in unmet demand. In these situations, CMS proposes to contact remaining contract suppliers to see if they could absorb the demand. If an unmet demand remains, CMS proposes then to refer to the list of suppliers that submitted a bid for that product category in that round of competitive bidding areas, use the list of composite bids that they arrayed in lowest to highest, and proceed to the next supplier on the list. This process would result in a single payment amount being developed using bids from suppliers that do not meet Medicare's standards. Instead, CMS should use 130% of capacity for the pivotal bid to provide greater assurance that the single bid price will be indicative of bids submitted by qualified suppliers in the event that a contract supplier is subsequently suspended or terminated from a competitive bidding program.

Determining Single Payment Amounts for Individual Items (Proposed §414.416): CMS proposes to determine the single payment amounts for individual items by using the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category. A necessary prerequisite is that CMS must first eliminate from all calculations information from bidding suppliers who don't meet all the quality and financial standards, and other requirements. Next, CMS needs to apply a test of reasonableness to all bids, and eliminate unreasonably high or low bids. Therefore, the single payment amount calculation should be based upon a review of all "reasonable" bids. This should provide a better representation of what the market price actually should be, rather than median of the lowest bids.

Invacare disagrees that the single payment amount should be based upon the median of supplier bids that are at or below the pivotal bid for each item. One must assume that each bidder is submitting its lowest possible bid in order to increase its chances of becoming a contract supplier. This methodology ensures that half of the contract suppliers will be forced to accept a bid amount that is less than their submitted bid. This will significantly increase the possibility that these suppliers will choose not to be a contract supplier, or will not be able to sustain their businesses if they do become a contract supplier. No winning bidder should be paid less than the amount of its bid. Instead, the single payment amount should be set at the pivotal bid amount, to ensure that beneficiaries will have access to suppliers who are able to sustain their businesses, and provide quality items and services.

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13. Rebate Program (Proposed §414.416(c))

In the NPRM, CMS proposes to allow contract suppliers who submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid amount and the single payment amount. CMS proposes that the rebate be voluntary but that contract suppliers cannot implement on a case-by-case basis. Contract suppliers would also be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals.

Invacare has serious concerns with this proposal and recommends that CMS eliminate the proposal in its entirety. This proposal is in direct conflict with the federal Medicare and Medicaid Anti-Kickback and Beneficiary Inducements laws, and we cannot understand how CMS can reconcile a rebate program with the clear statutory prohibition on beneficiary inducements under Section 1128A(a)(5) of the Social Security Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

This practice would clearly be illegal under this law if the supplier were to directly communicate a rebate to the beneficiary. The illegality is not corrected simply because the contract supplier is not the entity directly communicating with the beneficiary.

If CMS is attempting to provide beneficiaries with information to make more informed decisions about their health care, then CMS should provide beneficiaries with information that is more relevant to that decision-making process. For example, CMS should provide beneficiaries with information related to consumer satisfaction surveys, which are a current requirement of accreditation organizations. This would enable beneficiaries to make qualitatively informed decisions. Health care decisions are never made purely on price; rather, consumers are interested in the quality of the items and services.

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Finally, allowing an illegal practice in the context of the competitive bidding program will only perpetuate the industry's cloud of fraud and abuse; CMS should not be fostering that perception through illegal means.

14. Terms of Contract (Proposed §414.422)

CMS states that the length of the contracts may be different for different product categories. Invacare strongly urges CMS to have the same length contract for all products in a particular competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As it is, there are numerous variables that these stakeholders will have to understand (which products are part of the competitive bid; the boundaries of the competitive bid, etc.), it will simply add significantly more confusion if there are different lengths of contracts for different product categories in the same geographic area.

Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding: CMS proposes to require that repairs or replacement of patient-owned items subject to competitive bidding must be furnished only by a contract supplier. Given the new Deficit Reduction Act provisions that will result in beneficiaries owning significantly more items of DME than currently, Invacare strongly recommends that CMS develop detailed repair and replacement codes that would be part of the bid process. This has not been necessary when many items of DME had been rental items. With increased beneficiary ownership, specific codes for repair of specific items will be necessary to submit bids for repairs, as well as to facilitate claims processing.

Change in Ownership (Proposed §414.422(d)): It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet applicable quality standards and other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

The proposal to restrict the acquisition of a winning supplier unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the supplier's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

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Termination of Contract: CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated.

15. Administrative or Judicial Review (§414.424)

We recommend that CMS ensure that procedures are in place for bidders to ensure that calculation related to its bids are reviewed for accuracy, and that there are appropriate procedures in place for suppliers to redress issues such as simple calculation errors. Further, CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

16. Opportunity for Participation by Small Suppliers (Proposed §414.418)

The statute states: "In developing procedures relating to bids ***and the awarding*** of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program...."[1] (emphasis added). Congress, therefore, desired CMS to take steps in the bid process as well and the awarding of contracts process, to take into account the particular needs of small business. This proposed regulation provides no meaningful implementation of this Congressional mandate. CMS defines a small business consistent with the Small Business Administration's definition of small business, but then has not identified one procedure relating to bids or the awarding of contracts that are specific to or geared to accommodate the particular needs of small business.

The one proposal CMS puts forth to try and address small business issues is networks. This network proposal, however, is not limited to small businesses, and, due to its cumbersome administrative and legal requirements, is not likely to be a realistic option for small business.

During PAOC meetings, PAOC members recommended a number of ways to address small business issues. For example, small suppliers should be subject to less costly financial standards requirements; but the proposed rule makes no mention of this.

Invacare recommends that CMS adopt concrete measures to address the needs of small business. Specifically, CMS should establish a certain volume in each geographic area to "set-aside" a meaningful volume of business dedicated for small business, as do many other federal agencies such as the Veterans Administration.

[1] 42 U.S.C. §1395w-3(b)(6)(D).

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17. Opportunity for Networks

CMS is proposing to allow suppliers the option to form networks for bidding purposes, with several criteria that would have to be met to be a recognized and valid network. Invacare has a number of concerns regarding this proposal; primarily that the proposal is complex and will be very difficult for small suppliers to be able to have the time to form a network and comply with all the requirements, given the aggressive implementation timeline CMS has indicated. We understand that it may take close to a year for a small group of suppliers to form a network. As a result, CMS's network proposal is not a practical option for small suppliers who want to participate in competitive bidding, unless CMS provides significantly more time between its announcement of the initial ten selected MSAs and the date by which suppliers will have to submit bids.

18. Physician Authorization/Treating Practitioners

CMS proposes to allow physicians and other treating practitioners to request a specific item, brand, or mode of delivery. When this occurs, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that can provide that item, or consult with the physician or treating practitioner is to find a suitable alternative product or mode of delivery for the beneficiary. While we understand this requirement is based in the Medicare Modernization Act, CMS should understand that this requirement is likely to increase suppliers' costs; as often the physician will be requiring the supplier to provide an item that is more costly than what the supplier may typically maintain in its inventory.

19. Gap Filling

Invacare applauds CMS' recognition of the inadequacies of CMS' current gap-filling methodology used to determine fees when new HCPCS codes are created. The gap filling formula has become less and less relevant, as the market prices for many home medical products have simply not kept pace with inflation in other economic sectors. We agree with CMS, "there is an inherent responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, while also being a prudent payer".

Procedural Issues: Invacare strongly recommends that CMS separate its proposal for changing its current gap fill methodology from its proposed regulation on competitive acquisition for certain DMEEPOS items. The gap-fill methodology and its replacement pertains to all new codes that are created outside of CMS' implementation of competitive acquisition; and deserves appropriate separate consideration, public comment and related procedures.

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Regarding a proposed replacement to the current gap fill methodology, Invacare recommends that CMS follow defined procedural rules when exercising this authority, similar to the process CMS has developed for its National Coverage Determination process. For example, CMS should ensure that the public is informed at the time CMS initiates the process, there is a formal opportunity for public input and a formal opportunity for CMS to respond to public comment; and that all of these processes occur during a defined time period. Importantly, CMS needs to establish meaningful appeal rights for affected parties. Finally, the process for determining fees for new codes needs to be transparent (e.g., CMS must disclose all sources of data it relies upon in its determination), and CMS must be accountable to affected parties. In addition, the process should include a process to "lookback" and determine whether CMS pricing decisions have impacted beneficiary access

CMS proposes to discontinue the practice of deflating supplier prices and manufacturers' suggested retail prices to the fee schedule base period. When fee schedule amounts are established based on pricing information, prices in effect at the time that the fee schedule amounts are established would be used. Invacare agrees with this proposal. When manufacturers establish pricing information, it is based upon a multitude of factors that contribute towards the cost of manufacturing and distributing that product. Invacare recommends that CMS must demonstrate why it believes MSRP information is inappropriate before it would be able to abandon MSRP information as a significant factor in establishing new reimbursement amounts.

We are encouraged to know that CMS recognizes that the current gap-filling methodology can have arbitrary results. We also agree that CMS should depart from the practice of "deflating" current MSRP to arrive at a gap-filled amount and that CMS should use the median current retail price for new items to establish the payment amount. We remain concerned, however, because the proposal for a technology assessment process is vague and lacks any opportunities for stakeholder participation. More importantly, CMS' only authority to adjust payment amounts for an item or a category of items is the IR authority under §1842(b)(8) and (9). Further, a number of stakeholders asked CMS to allow an expanded comment period for this issue specifically so that we can provide CMS with thoughtful recommendations on how to proceed. We reiterate that request.

The IR methodology established by Congress requires CMS to make a determination that using the "standard rules for calculating payment" results in a payment amount that is not inherently reasonable. Congress directed the Secretary to identify the factors that it would use to determine when a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. In determining whether a payment amount is not inherently reasonable, and in establishing a new payment amount, CMS or its contractors must use "valid and reliable data" that meets specific criteria applicable to the

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data collection and analysis. 42 C. F. R. §405.502 (g). Importantly, the IR methodology contains specific procedural safeguards that apply to any determination to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, one factor CMS must consider (among others) is the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates." §1842b (8) (C).

CMS' proposal to use a technology assessment process to adjust payment amounts would allow CMS to avoid the explicit requirements under §1842b and its implementing regulations simply by migrating existing products into new HCPCS codes. Congress included the requirements for notice and comment and the use of valid and reliable data under the IR methodology in order to protect the interest of beneficiaries and providers from poorly conceived payment reductions that can affect access. CMS cannot use a technology assessment to make a payment adjustment based on a determination that a payment amount does not "reflect the cost of furnishing the item" as the proposed rule states because those factors cannot serve as the basis for a special payment adjustment under §1842b (8) and (9).[2]

We strongly oppose CMS' proposal to use a technology assessment process to establish fees for new HCPCS codes. This process inappropriately combines coding, coverage and payment issues; processes that have for good reason been separate. However, to the extent that CMS intends to use the technology assessment to establish a payment amount or a new HCPCS code for new products, we recommend that CMS include notice to affected stakeholders and an opportunity to participate in the process.

We agree that CMS should establish fee schedule amounts for new products using the median retail price for the item or the fee schedule amounts for comparable items. Moreover, we recommend that if CMS believes retail prices are inappropriate, then CMS must demonstrate why it believes that is the case, before it employs an alternate methodology to establish pricing. Retail pricing is probably the best indicator of the appropriate market price.

CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment

[2] It is important to note that the technology assessment CMS proposes does not and cannot include any information to assess the cost of furnishing an item to a beneficiary. The criteria proposed for the technology assessment focus on a cost benefit analysis of the technology relative to other similar products. This analysis is different from an analysis of provider costs to furnish the product which would include not only the acquisition cost of the product, but also the cost of servicing the beneficiary, the cost of accreditation and other regulatory compliance, as well documentation, billing, and other costs.

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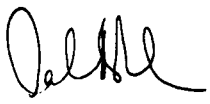
amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. Invacare strongly opposes this proposal because it is based on the unfounded assumption that the items in the two new HCPCS are comparable with comparable appropriate prices. When a HCPCS code is divided into two or more codes, the most likely rationale is that there exist significant enough differences in the technology to warrant different codes and hence different prices.

* * * * *

Thank you for the opportunity to provide comments on this important proposed regulation. Invacare is happy to discuss these issues in further detail. Please contact Cara Bachenheimer at 440-329-6226, or via electronic mail at cbachenheimer@invacare.com.

Sincerely,



Cara C. Bachenheimer

Vice President of Government Relations

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BURLINGTON PODIATRY ASSOCIATES
DAVID J. CARROLL, D.P.M.
BOARD CERTIFIED - AMERICAN BOARD OF PODIATRIC SURGERY

6-27-06

Dear Dr. Mc Clellan,

I write today to urge CMS to allow podiatrists to competitively bid to supply DMEPOS only to their patients. As a physician in the medicare program I ask the same rights afforded an MD or DO. With this in mind I urge CMS to use the 1861(r)(3) definition of physician.

My patients deserve the access to DME's in my office. It affords them prompt, appropriate, professional care for a wide variety of problems that can be treated in the out-patient setting.

ex. Simple Hammer toe repair can be safely performed in the office. As you know, this saves thousands of dollars, compared to out patient surgery at the Hospital. I should be able to dispense crutches and a surgical shoe for these patients.

Please do the right thing!! Sincerely,

281 CAMBRIDGE STREET
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781-272-1040

955 MAIN STREET
WINCHESTER, MA 01890
781-729-6773

500 SALEM STREET
WILMINGTON, MA 01887
978-988-6246

FAX 781-270-9072

193

Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Crowne Health Care of Montgomery, LLC, located in Montgomery, AL. Crowne Health Care of Montgomery is a 185 facility with approximately 220 employees, our services include skilled nursing services as well as therapy services.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care of Montgomery we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,
Wanda Suggs

Crowne Health Care of Montgomery, LLC • 1837 Upper Wetumpka Road • Montgomery, Alabama 36107 • (334) 264-8416

194

American Academy of Physical Medicine and Rehabilitation

aaPM&R

330 N. Wabash Avenue, Suite 2000
Chicago, Illinois 60611-5832
www.aapmr.org

June 28, 2006

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1849

Re: Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics and Supplies; CMS-1270-P.

Dear Dr. McClellan:

The American Academy of Physical Medicine and Rehabilitation (AAPMR) appreciates this opportunity to comment on the proposed rule establishing a competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The AAPM&R is the national medical society representing over 7,000 physiatrists, physicians who are specialists in the field of physical medicine and rehabilitation.

Crutches, Canes and Walkers

Physicians specializing in physical medicine and rehabilitation (also known as physiatrists) often treat patients with musculo-skeletal conditions many of whom have injuries or mobility impairments. Often these patients have difficulty walking and may have considerable pain. It is common practice for physiatrists treating such patients to dispense directly from their office items such as crutches, canes, and walkers. This saves the patient the inconvenience and possibly extra pain and suffering of having to obtain these products elsewhere. We are extremely concerned that the proposed rule will make it impossible for physiatrists to continue to provide these items to patients who need them and instead patients will be required to travel to vendor sites. For the frail elderly Medicare population, this would indeed be a disservice. [1]

In order to preserve patient access to these low cost but essential items, AAPM&R urges that CMS establish an exception from the competitive bidding program. In this regard, we point out that CMS has already recognized the importance of allowing physicians to dispense these items directly to patients in the context of the exceptions to the physician self-referral or "Stark" law. The Stark law regulations specifically permit physicians to self-refer for crutches, canes, walkers and folding manual wheelchairs. 42 C.F.R. Section 411.355. We believe it is essential that a similar exception apply to the competitive bidding rule.

[1] Although we understand that physicians are permitted to submit bids to be DMEPOS vendors, most physician practices would not want to provide all the items that the proposed rule would require of potential vendors and, moreover, would be constrained from doing so under the Stark law.

aaPM&R

Orthotics

AAPM&R also believes an exception must be made for certain low cost off-the-shelf orthotics including splints for fractures and sprains, spinal stabilization braces, corsets, rib belts cervical collars and other similar low cost items. Currently, many physiatrists dispense these items directly to the patient. This not only saves the patient the burden and inconvenience of having to travel elsewhere, but has the added benefit of allowing the physician to exercise some quality control over the product and, more importantly, to ensure that it is properly fitted. This reduces the possibility that the patient will obtain a product that does not fit properly and is therefore ineffective. For example, if a physiatrist sees a patient who has been in a motor vehicle accident and has a neck spasm, the patient should be able to receive a cervical collar directly from the physician and not be required to drive around looking for one. Similarly, if a patient needs a wrist splint, by dispensing it directly from the office, the physiatrist can ensure that it fits properly and does not cause pain. This would be a particular hardship for patients in rural areas who may have to drive considerable distances to find their Medicare approved DME vendor; it would also be a hardship for low-income Medicare beneficiaries who may not have access to a car or other readily accessible means of transportation.

If an exception is not made for these relatively low-cost items for which there is acute need, Medicare beneficiaries will undergo needless suffering and inconvenience. For this reason, we strongly urge that the proposed regulations be amended.

Vendor/Physician Arrangements

AAPM&R also requests that CMS clarify that there is nothing in the rule that prohibits DMEPOS vendors from providing physicians with these items as inventory which the physician can then dispense directly to the patient with billing to be done by the vendor. Assuming such arrangements are consistent with other Medicare laws such as the anti-kickback law, they should be permitted. We ask that CMS clarify that this is the case.

We appreciate the opportunity to submit these comments. If you have any questions please contact Dawn Brennaman, MPA, AAPM&R's Director of Health Policy and Practice Services at 312-464-9700.

Sincerely,

Steven M. Gnatz, MD
AAPM&R President

Gerald N. Rogan, MD, Consulting
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jerryroganmd@sbcglobal.net

June 29, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Comments to Proposed Rule CMS-1270-P: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Recommendation: In the Final Rule implement an additional program safeguard requirement that is likely to increase assurance that all DME items provided are *reasonable and necessary* to treat the beneficiary.
Rationale Summary: Competitive bidding will reduce the overpayment driver of waste, abuse, and fraud. Mandatory compliance will increase effective program safeguards.

Dear CMS:

I propose the following additions (**bold**) to the Final Rule under the following comment headings:

- Conditions for Awarding Contracts (Proposed §414.414)
- Terms of Contract (Proposed §414.422)

Recommendations for Incorporation into Final Rule CMS-1270:

1. §414.414: Conditions for awarding contracts.: (c) Quality standards and accreditation.
    a. Recommendation: Add an additional section **(3) *Compliance program.* All bidding suppliers must include in their bid a compliance program designed to assure that the items provided to beneficiaries are *reasonable and necessary* consistent with the purpose for which the item is prescribed by the referring (treating) practitioner.**
    b. CMS should consider whether to specify in the regulation that --- **CMS reserves the right to consider factors other than price to award a contract (e.g. the quality of a compliance program: the likelihood that**

a bidder's compliance program will assure services provided are *reasonable and necessary*).

2. §414.422: Terms of contracts.:
Recommendation: Add to *(a) A contract supplier must comply with all terms of its contract, including any option exercised by CMS,* **including but not limited to contract award conditions specified in §414.414(c),** *for the full duration of the contract period.*

Rationale: These proposals may further effectuate the intent the following goals articulated in the regulation:

- Improve the efficient interaction among manufacturers, providers of services, suppliers, and individuals;[1]
- Increase oversight of product provision[2] in an efficient manner that includes provider innovations consistent with sound business practices and recommendation of the OEI/OIG;[3]
- In addition to requiring specified quality standards and accreditation[4], provide for additional accountability and business integrity through a readily auditable program to assure that the items supplied to beneficiaries are *reasonable and necessary*;[5]
- Encourage DME suppliers to optimize information management techniques that meet these goals;[6]
- Encourage and reward DME suppliers that contribute to an improvement of net health outcomes by facilitating the communication of the results of diagnostic tests (performed with DME supplies) to the referring practitioner to support superior decision-making;[7]
- Assure that DME supplier eligibility fulfills the OEI/OIG recommendations that CMS supports: those that are likely to help assure DME items supplied to beneficiaries are *reasonable and necessary* (i.e. are not compromised by fraud, abuse, or waste);[8]

In order to assure savings under the Medicare DMEPOS Competitive Bid Program, CMS should consider whether a bidder's robust compliance program, fully effectuated and proven effective by independent audit, may substantially assure the affected DME items provided are *reasonable and necessary*, even when the payment for a few individual items within a product category is higher than the allowable established by the *Pivotal*

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[1] CMS-1270-P page 25658
[2] CMS-1270-P page 25659
[3] OEI-03-98-00230; June 2000; OEI-03-98-00231; June 2000
[4] CMS-1270-P §414.414 (c)(1) and (c)(2) page 25700
[5] CMS-1270-P page 25659
[6] Ibid.
[7] CMS-1270-P page 25671: "compete on quality for business"
[8] CMS-1270-P page 25675: "bidders must meet eligibility rules"

Bid.[9] If CMS agrees with this intent, the Final Rule should permit CMS to consider the value of a provider's compliance program designed to assure statutory *reasonable and necessary* requirements are met[10]. CMS may wish to consider non-price variables when awarding contracts for certain DMEPOS items.

For example, the Final Rule should allow CMS to consider the value of innovative business models that are likely to assure that DME supplies provided to beneficiaries are *reasonable and necessary*[11], including:

a. Assurance that DME supplies for self-administered tests are used by the beneficiary for illness management;
b. Assurance the practitioner who orders the supplies is regularly informed of the beneficiary's self-management test activity; and
c. A method by which DHHS agencies may readily audit the activities of the DME supplier to assure its compliance with contract requirements.

ABt Associates recommended parameters of (1) business quality standards and (2) product quality standards.[12] I believe the ABt recommendations do not go far enough to meet the needs of program integrity outlined by the OEI/OIG and agreed upon by the Agency.[13] The OEI/OIG recommends a voluntary DME compliance program. My suggestion is that CMS makes the compliance program mandatory. The Agency would promote concurrence and cooperation with the OEI recommendations by requiring a DME supplier to provide a *compliance program* as part of its bid. In addition, CMS should retain the authority to measure the value of the compliance program based on the likelihood compliance is assured, the ease with which CMS may audit the compliance, and other additional benefits the compliance proposal can bring to the Program to reduce cost and improve health outcomes. Bids by suppliers who adopt such approaches would offer CMS the opportunity to create net savings from factors other than a low-bid based model alone.

Specifically, the value could be measured by evaluating whether

- The supplies are delivered to the beneficiary;
- The supplies are *reasonable and necessary*;
- The supplies are used as part of medical decision making by the patient and/or practitioner;
- All documentation requirements are met;
- Other recommendations promulgated by OEI/OIG/DHHS and agreed upon by the Agency are met;

---

[9] CMS-1270-P page 25678: "During the demonstration, several product categories received overall savings, whereas payment amounts increased for a few individual items within those product categories."
[10] Section 1862(a)(1)(A) of the Act.
[11] Under §1862(a)(1)(A) of the Social Security Act of 1965 and related statutes and regulations.
[12] Quality Standards for Suppliers of Durable Medical Equipment, Prostehtics, Orthotics, Supplies (DMEPOS) and Other Items and Services: Draft of Proposed Recommendations, September 26, 2005, page 1.
[13] OEI-03-98-00230; June 2000; OEI-03-98-00231; June 2000

- The method the DME supplier will use will assure compliance;
- The DHHS agencies may easily audit the DME supplier for compliance; and
- The DME proposal can measure and report to appropriate stakeholders the contribution the DME supplies make to improve health outcomes of the beneficiaries.

For example, if a non-insulin diabetic self-tests his/her blood glucose the following data would be helpful to determine whether ongoing test supplies are *reasonable and necessary*:

1. How often is self-testing performed?
2. Is the referring practitioner aware of the results and patient self-management?
3. Are the test results used to help diabetes management?

Taxpayers through Congress provide a comprehensive medical benefit to those who are over 65 or disabled. The cost of the program is substantial. Some taxes for the Program are paid by working individuals without illness and injury insurance and young children to rear. All providers who are paid by the Medicare Program enter into a legal contract as well as a social covenant to respect the Program and adhere to its statues, regulations, and rules—both explicit provisions and implicit expectations. The fraud, abuse, and waste documented in the OEI/OIG reports are unacceptable. All providers are expected to comply with Medicare rules, and agree to do so at the time of provider enrollment. Therefore, a voluntary compliance program seems insufficient, as opposed to a mandatory program. I suggest a robust compliance program is a reasonable additional requirement for a DME company that enjoys guaranteed payment for an item or service covered by the Program. By requiring compliance and a compliance program for all bidders, the cost of compliance will be part of the payment. The field of competition will remain level, with greater likelihood of compliance. A rationale objection to a mandatory compliance requirement applicable to all DME suppliers escapes me.

By assuring payment will be made only for *reasonable and necessary* items and services, compliance may assure savings greater than that achieved by price reductions alone. CMS should retain the discretion to determine the likely value a particular supplier's compliance program brings Medicare and consider its value as an independent variable for contract award.

Respectfully Submitted:

Gerald N. Rogan, MD
Medicare Consultant

About the commenter:

In my role as the Medical Director for the largest Part B carrier in the country, NHIC CA (1997-2003), I was honored to focus carrier resources to help identify practical safeguard solutions to reduce Program vulnerability to fraud, waste and abuse; and underscore to practitioners the unique value the Program brings to their practices and their patients. From this experience I found that Medicare's total cost for a particular benefit was directly proportional to the amount by which a payment exceeds the reasonable cost to provide an item or service and indirectly proportional to the effectiveness of the program safeguard activity associated with the benefit. I found the "pay and chase" method to protect the Program is suboptimal. For DME, competitive bidding will reduce the overpayment driver. Mandatory compliance will increase effective program safeguards.

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June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. McClellan:

Option Care of Camilla, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Option Care of Camilla, Inc. is located in Camilla, Georgia and has been in business for 20 years. We specialize in durable medical equipment, orthotics, infusion therapy, enteral nutrition therapy, and supplies. We provide equipment & these therapies to thousands of patients in the rural area of South West Georgia. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes. The new competitive bidding initiative will put my business and many other companies on the brink of bankruptcy.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 229-336-7758.

Sincerely,

J. Harris Morgan, RPh
President

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

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of East and Central Iowa
option home health

196-1

June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Option Care of East and Central Iowa is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Option Care of East and Central Iowa is located in Cedar Rapids, Iowa. We service patients in central and eastern Iowa. We are an employee owned company and have been in the home infusion and comprehensive home care business for the past 25 years. We are accredited by the Joint Commission. Our team of expert clinicians includes a nutrition support and IV certified nurse with 25 years experience, the only Board certified nutrition support pharmacist in Iowa and many other specialty trained nurses, pharmacists (PharmD and Masters Prepared), dietitians, and other essential support staff. We are an Option Care Center of Excellence in Nutrition Support and Heart Failure and have cared for hundreds of Medicare patients requiring enteral and total parenteral nutrition as well as other infusion therapies.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging

undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there

would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 319-363-1284.

Sincerely,

Shari Mailander

Shari Mailander, RN, CCM
Owner/Chief Operations Officer

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

197

KENDALL P. TABOR, D.P.M., F.A.C.F.S.

Foot Specialist and Foot Surgeon
Diplomate, American Board of Podiatric Surgery
Certified in Foot Surgery

1414 W. Fair Ave. Suite 50
Marquette, MI 49855
Telephone: (906) 225-7709

June 26, 2006

Mark B. McClellan, M.D., PhD
Administrator
Centers for Medicare & Medicaid
Dept. of Health & Human Services
7500 Security Blvd.
Baltimore, MD 21244

Attention: CMS-1270-P

Dear Dr. McClellan:

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for durable medical equipment.

This rule, if implemented, would limit my ability to supply rapid, quality care to my patients. I urge the Centers for Medicare & Medicaid Services to at least exclude physician services from the competitive acquisition program.

If a patient presents with a fracture, we can immediately dispense a fracture walker, rather than having to send him 50 miles to another supplier (we are in a rural area). Diabetics with ulcers on their feet and/or deformities can obtain therapeutic shoes in our office without a third-party involved, which makes obtaining adjustments and repair difficult.

Sincerely,

Kendall Tabor, D.P.M.

KPT:s

198

Empi®
Your Partner in Rehabilitation Outcomes

Rec'd 6/29/06

June 26, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1270-P

Re: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Administrator McClellan:

Empi, Inc. ("Empi") is pleased to have the opportunity to comment on the proposed rule, CMS-12710-P, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and Other Issues. Empi is the leading Medicare provider of transcutaneous electrical nerve stimulation ("TENS") device which are used to relieve pain and promote recovery. Empi respectfully requests that the Centers for Medicare and Medicaid Services ("CMS") exercise its statutory discretion to not select TENS devices as one of the initial product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program. As we explain below, including TENS devices in the 2007 phase-in would force CMS to try to configure a competitive bidding program best suited for commodity type products into one dealing with differentiable products, which could compel many beneficiaries to use inferior TENS products without achieving measurable savings for the Medicare program. Since we understand the policy directive you have been charged with, which is to attempt to lower health care costs while preserving quality, we look forward to working with CMS on the continued implementation of the competitive bidding program and the specifics of the TENS market.

Background: TENS and Empi

TENS is an FDA Class II medical device that employs low-level electrical stimulation to relieve pain and promote recovery. TENS is most commonly used to treat back pain, but is also effective for the treatment of arthritis, strains and sprains, and neuralgia, among other conditions. TENS is frequently prescribed as an adjunct to physical therapy for conditions related to chronic pain and post-surgical or post-trauma acute pain. TENS works in two ways: first, by using

599 Cardigan Road • St. Paul, MN 55126-4099 Tel: 651.415.9000 FAX: 651.415.8535 www.empi.com

electrical stimulation to disrupt the body's transmission of pain messages; and second, when the stimulation is sufficiently intense to cause mild muscle twitching, by inducing the body to produce its own natural pain reliever, a neurohormone called endorphin.

TENS provides patients and clinicians with a safe and cost-effective alternative to drugs for the relief of pain. And, given the removal of Vioxx™ and Bextra™ from the market during the latter part of '04 and early '05, physicians are faced with an increasingly limited armentarium of pain interventions. The result is a national health care crisis resulting from physical dependence and addiction to opiates and narcotics. In the U.S., more than 200 million prescriptions are written for opiates such as Oxycontin™ each year (Dendrite International 2004). The direct and indirect cost associated with these medications can be reduced by increased reliance on non-systemic interventions such as TENS.

Empi is a market-leading manufacturer of electrotherapy devices based in St. Paul, Minnesota, with facilities in South Dakota, Kentucky and Florida, and is the leading Medicare provider of TENS devices. Empi's digital Epix VT uses a microprocessor to store twelve distinct pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients and to make the devices easy to use by patients. The Epix VT is the only available TENS device to incorporate this feature. The Epix VT is also the only TENS device on the market to feature biosourced, biaphasic waveform, which ensures the constancy of the electrical stimulus, and provides an additional measure of patient comfort and safety. These unique features make the Epix VT the most popular TENS device on the market.

Finally, Empi is the only TENS manufacturer to provide periodic post-sale monitoring of its devices, an essential product support service. Empi provides TENS devices to over 187,300 patients per year with an effective, low cost pain therapy treatment, which is in many cases a preferred alternative to prescription drugs which have systemic side effects and potentially higher costs. In addition, to support these devices and this service level, Empi has developed nationwide service capabilities and a robust and on-going research and development program to continue to improve the products.

The Proposed Rule: Selection of DMEPOS Product Categories

As the Proposed Rule observes, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") "mandates a larger role for competitive bidding within the Medicare program," including the establishment by the Secretary of Health and Human Services ("HHS") of "competitive bidding programs for the furnishing of certain DME and associated supplies."[1] Section 1847(a)(1)(B)(ii) of the Social Security Act (the "Act") gives CMS the authority to phase in the competitive bidding program with its direction to focus, "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential."[2]

Among the factors that CMS proposes to weigh in "making determinations about an item's potential savings as a result of the application of competitive bidding," are different items'

[1] 71 Fed. Reg. 25657 (May 1, 2006).
[2] 42 U.S.C. 1395w-3(a)(1)(B)(ii).

annual Medicare DMEPOS allowed charges.[3] CMS estimates that "approximately 10 product categories will be selected for competitive bidding for 2006 and as many as 7 or 8 of the selected product categories will be among the 10 largest in terms of allowed charges. The remaining 2 or 3 product categories will come from the top 20 eligible DMEPOS policy groups and their 2003 allowed charges."[4]

TENS Devices Should not be Subject to Competitive Bidding in 2007

CMS should exercise its discretion under Section 1847(a)(1)(B)(ii) of the Act to exclude TENS devices from the 2007 phase-in of the competitive bidding program for several reasons. First, TENS devices in fact constitute a miniscule percentage of Medicare charges. Second, because until CMS has a better understanding of how to do competitive bidding in a non-commodity environment, the competitive bidding program defies the wide variation in quality—and, accordingly, price—within the TENS device market. By grouping all TENS devices within a single product category for the purpose of competitive bidding this will induce many patients to purchase inferior devices. Third, some TENS device manufacturers, including Empi, include within the cost of their devices a post-sale periodic monitoring services to ensure that the device is functioning properly. Low-cost providers generally do not. This would further complicate the nature of competitive bidding since not every medical device company would be offering similar products when they were to make their bid.

1. TENS Devices are a Low-Volume Product Category Relative to Other DME

The total allowed Medicare charges for TENS devices is very small relative to other DME products, with annual expenditures of approximately $10 to $15 million. Indeed, as Table 4 in the Proposed Rule indicates, TENS devices constituted less than one-tenth of one percent of allowed Medicare charges for DMPOS. Nor are TENS devices among the twenty-four highest volume DME items listed in Table 3 of the Proposed Rule.[5] Moreover, the overwhelming majority of DMEPOS reimbursed by Medicare are compressed into a very few high-volume product categories. According to the Proposed Rule, the top five categories alone account for a full 77% of allowed Medicare charges, with proportionate volume declining dramatically thereafter. Several policy groups, such as oxygen, wheelchairs, and diabetic supplies have charges in excess of $1 billion. Indeed, TENS devices, at number 20 on the list, account for only .4% of the charge volume of the fifth-ranked product category, Hospital Beds/Accessories, and about 12% of the charge volume of the tenth-ranked product category, Lower Limb Orthoses. As such numbers suggest, TENS devices are not among Medicare's "highest cost and highest volume" DMEPOS items, and do not offer the program substantial "savings potential," as required by the Act.

2. Including TENS Devices Within the First Phase of the Medicare Competitive Bidding Program Will Compel Many Patients to Purchase Inferior Devices

[3] 71 Fed. Reg. at 25671.
[4] *Id.* at 25691.
[5] *Id.* at 25670.

Available TENS device vary widely in quality and technological sophistication; accordingly, the market is properly stratified by price. We are concerned that the competitive bidding program is not yet structured to take into account these variances and we believe that it will require a significant amount of planning and development to design the program to be effective in achieving the dual goals of saving money while providing consumers with appropriate high-quality healthcare. As we described above, Empi's digital Epix VT uses a microprocessor to store twelve different pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients. This kind of customization is unavailable on the typically imported non-digital devices with which Epix VT competes. The same features that make the Epix VT the most popular TENS device, however, even with the advances in technology, also make it more costly to manufacture, and hence, by necessity, more expensive. Empi simply cannot and should not compete on price with the low-cost, technologically inferior, imported devices. To require Empi to do so by including TENS devices in the 2007 phase-in of competitive bidding before the sophistication of competitive bidding processes can be developed after seeing how the market reacts to competitive bidding in the easier commodity product categories would be to treat as fungible products that, in reality, are highly differentiated in terms of clinical efficacy. Inferior devices will prevail in a poorly designed competitive acquisition process, and as a result patients will receive sub-optimal therapy.

3. Many TENS Device Manufactures do not Provide Periodic Service and Monitoring of Their Devices

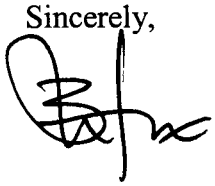
Finally, Empi provides post-sale periodic service monitoring of its Epix VT devices in order to ensure that they continue to function properly. By contrast, many of the low-cost TENS device manufacturers do not offer this important service. As in the case of pre-programmable therapy regiments, this feature contributes to the relatively higher cost of the Epix VT. Again, by treating as fungible TENS devices, such as the Epix VT, that include this important monitoring service and less expensive devices that do not, a competitive bidding process that is not properly designed to take into account this service component would ensure that many Medicare patients are deprived of a superior product.

For the reasons outlined above, primariliy that including TENS devices in the 2007 phase-in portion of the competitive bidding program would not result in measurable savings to the Medicare program, TENS devices should not be part of the phase-in program. Including TENS could also put in place a competitive bidding system that could have as an unintended consequence of an appropriate policy initiative, the result that many beneficiaries would be compelled to use inferior TENS product. CMS should therefore exercise its statutory discretion to not select TENS devices as one of the ten product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program.

We look forward to working with CMS over the next two years on refinements to the Competitive Bidding Program to ensure that beneficiaries will have access to high quality TENS devices and that a competitive bidding scenario can be developed that works in a non-commodity marketplace. We would be happy to meet with your staff to discuss TENS products and their Medicare market in more detail and to continue to provide assistance in developing ways to

lower Americans' healthcare cost while providing the high-quality, technologically advanced medical devices Americans deserve and desire.

Sincerely,



Barry Hix, MBA, MPH
Vice President – Marketing and National Accounts

Harry L. Zimmerman
Executive Vice President – General Counsel

cc: Laurence Wilson, Director, Chronic Care Policy Group

1199-0
(5)

Responsive Solutions Inc.
HOME INFUSION SERVICES™

June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
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Baltimore, Maryland 21244

4605 Oleander Drive
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File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Responsive Solutions, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

We are a small to medium sized home infusion pharmacy that offers infusion devices (infusion pumps) for patients we serve in our geographical area. We have a high density of retirees in our area since we are a resort / retirement destination. The Medicare population that we serve continues to grow yearly as more retirees move to our area and thus our negative exposure to competitive bidding. We have been in business in this area since 1994.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

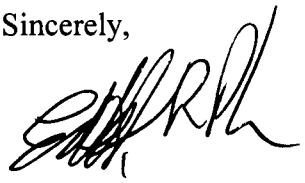
   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 843-497-5433.

Sincerely,



Ed Hewitt, RPh
Co-owner

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

Responsive Solutions Inc.
HOME INFUSION SERVICES™

1991-1

June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

4605 Oleander Drive
Suite 5
Myrtle Beach, SC
29577

(843) 497-5433
fax (843) 497-5432
pager (843) 477-3784
www.responsive-solutions.com

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Responsive Solutions, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

We are a small to medium sized home infusion pharmacy that offers infusion devices (infusion pumps) for patients we serve in our geographical area. We have a high density of retirees in our area since we are a resort / retirement destination. The Medicare population that we serve continues to grow yearly as more retirees move to our area and thus our negative exposure to competitive bidding. We have been in business in this area since 1994.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 843-497-5433.

Sincerely,

Conrad Banks, RPh
President/Co-owner

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

199-2

Birmingham Medical Alliance, Inc.
194 Narrows Drive Ste 2
Birmingham, AL 35242-8604

June 27, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Birmingham Medical Alliance, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Birmingham Medical Alliance is a small Woman Owned DMEPOS provider that has been in business since 2002.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

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CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

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Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 205-991-0413.

Sincerely,

Georgia Lay

Georgia Lay
President

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

1199-3

Riverside Medical Ctr/Home Infusion
500 North Wall Street, Suite 400
Kankakee, IL 60901

June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Riverside Medical Center/Home Infusion is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Riverside Medical Center/Home Infusion is located 60 miles south of Chicago in Kankakee County. We service our community for their Home Infusion needs. We have a monthly average of 64 patients a month of which 85% are Medicare/Medicaid patients.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In

addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 815-935-7256 extension 3246.

Sincerely,

Peggy Regas

Peggy Regas
Financial/Billing Coordinator
Riverside Home Infusion

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

199-4

NewLife HOMECARE, INC.

1-877-707-LIFE

June 30, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

New Life Home care, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

New Life Home Care, Inc. is a specialty pharmacy located at 48 South Main Street, Pittston, Pa. 18640. Our pharmacy services clients with bleeding disorders, such as Hemophilia and Von Willebrands. Several of our clients are on Medicare. Our clients have life threatening chronic conditions and require their medications to survive.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 570-602-3093.

Sincerely,

Sally Roper

Sally Roper
Director TQM/HR

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

RX Pharmacy Services

200

Main Office
540 Seco Road
Monroeville, PA 15146

June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

RX Pharmacy Services and Mosso's Medical Supply Company are pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

RX Pharmacy Services is a Home Infusion Company with approximately 100 employees and 1,200 patients. Mosso's Medical Supply is a RT/DME Company with 140 employees and Approximately 7,000 patients. Both businesses are owned by Air Products Healthcare and are located in Western Pennsylvania. As a business leader, I am proud to tell you that my organization and it's employees provide only the highest level of clinical services to the patients that are under our care. Implementation of the competitive bidding is an indicator that CMS is looking for the cheapest price without concern for the clinical services provided to the patient. There are many companies in our area that provide lower service levels to patients in an effort to increase there profits. We however, consistently search for opportunities to become more efficient and maintain our level of services to the patient. While CMS has considered the quality standards in its process, there are different levels of quality in our industry. The competitive bidding process gives an edge to the providers that provide less services (commodity) with lower costs resulting from less service

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging

undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

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3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

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would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

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Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 412-702-0209.

Sincerely,

Jeffrey Kreutzer
Division President, RX Pharmacy Services & Mosso's Medical Supply

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

NHC
NATIONAL HEALTHCARE CORPORATION

201

June 29, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and other issues (42 CFR Part 411, 414, and 424).

To Whom It May Concern:

On behalf of National HealthCare Corporation (NHC) (a multi-facility long-term care company), as Senior Vice President of Patient Services, I am writing to comment on the Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and other issues (42 CFR Part 411, 414, and 424).

We strongly believe that Skilled Nursing Facilities (SNFs) should be excluded from the Competitive Acquisition Program. There are very strong practical issues from a nursing and facility perspective that must be considered. As a nurse, I can only imagine the confusion that the competitive acquisition rules will cause and how this confusion will disrupt care and services for nursing home residents.

1. The rules do not address the monitoring of multiple beneficiaries as occurs in a nursing facility; furthermore the rules are incompatible with plan of care requirements imposed on nursing homes:
    a. First and foremost, home patients have individual caretakers that monitor and communicate with suppliers, thus protecting the privacy of **one** patient and monitoring the quality of the service and equipment for **one** patient. This is a fairly easy process.
    b. SNFs, in comparison, have limited personnel to communicate for **many** patients in the facilities and must monitor the quality of supplies and privacy of **multiple** patients. The place of service the supplies are delivered makes a significant difference in the ease of monitoring the supplier.

2. Our SNFs use **one** supplier that furnishes enteral, urological, tracheostomy, ostomy, and, sometimes, surgical dressings. Nurses, bookkeepers, purchasing staff, and administration communicate with this one supplier about multiple patients. Competitive Acquisition might result in multiple suppliers furnishing limited supplies to multiple patients. Multiple suppliers furnishing to multiple patients would each have procedures for ordering and handling exceptions; this would cause an unnecessary burden on the center nursing staff.

3. I would expect confusion if we must fax new orders for supplies to multiple suppliers for multiple patients. This would be similar to faxing prescriptions to multiple pharmacies, depending on the drug ordered.

4. SNFs may experience increased liability as new suppliers may furnish unfamiliar products (different manufacturers) using unfamiliar personnel that may, or may not train on all three shifts in the SNFs. Training multiple caregivers on multiple shifts may present a new challenge for suppliers that have only provided home care.

5. Currently NHC centers dealing with one supplier receive all supplies in one delivery on a periodic basis that is convenient for the SNFs. With the introduction of several suppliers and different delivery schedules, SNFs will be required to spend more time monitoring the suppliers' activities in their facilities and the availability of products from multiple vendors.

6. Patients in SNFs have a higher acuity than patients at home. Our suppliers must have a wide variety of disease-specific enteral products available on short notice, and must be able to communicate knowledgeably with the professionals providing the care.

We think it will be mutually beneficial to CMS and to SNFs to manage these services differently than the way you propose in the regulations. SNF/NF settings are different than the home setting. Will you please consider excluding SNF/NF settings from the competitive bidding process?

Thank you for allowing me to voice my concerns. I hope we will avoid unintended consequences for SNF staff.

Sincerely,

Julia W. Powell, BSN, MA
Senior Vice President, Patient Services

cc: Mike Ussery

Board for Orthotist/Prosthetist Certification
THE ADVANTAGE IS EXPERIENCE™

Board for Orthotist/Prosthetist Certification
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Baltimore, Maryland 21201
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June 30, 2006

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attn: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on Proposed Rule CMS-1270-P

Dear Dr. McClellan:

We are writing on behalf of the Board for Orthotist/Prosthetist Certification (BOC) in order to expand upon and clarify the points made by Donald O. Fedder in his letter to you dated June 13, 2006, regarding the proposed Competitive Bidding Rule. We appreciate this ongoing opportunity to dialogue with CMS and to provide comment regarding the proposed rule.

Off-the-Shelf (OTS) Orthoses

In Dr. Fedder's letter, he discussed the provision of certain off-the-shelf (OTS) devices in relation to the services of Certified Orthotic Fitters (COF) and Certified Mastectomy Fitters (CMF). While the BOC generally stands by the points outlined within the letter, we would like to clarify certain terms and issues addressed by Dr. Fedder.

In keeping with the language in the proposed rule, the term off-the-shelf (OTS) should be used to describe only those items that are ready-made and may be provided to a patient with minimal or no adjustment or customization for appropriate use. Such items may be literally taken from the box and provided to the patient "as is", and require no expertise for fitting or dispensing. While all OTS orthoses are "prefabricated", not all prefabricated orthoses are OTS. The proposed terms "Fitted High" and "Fitted Low" do not apply to OTS orthoses; rather, these terms refer to prefabricated orthoses that require the expertise of a trained, credentialed practitioner in order to properly fit and dispense. Prefabricated orthoses are not *custom made* for a specific patient, they are *customized* and intimately fit based on an individual patient's measurements. Custom fitted (high and low) prefabricated orthoses require varying degrees of customization and are appropriate only when properly customized by a trained and credentialed individual.

The Certified Orthotic Fitter (COF) credentialed practitioner is qualified to provide professional service to patients in need of custom fitted prefabricated devices. Secondarily, the BOC's Certified Orthotic Fitters (COFs) have been determined by National Commission for Certifying Agencies (NCCA) standards to be independent practitioners specializing in the dispensing of prefabricated custom fitted devices. Custom Fitted orthotic services require the COF to assess the patient's condition, determine the appropriateness of the prescription and custom fit prefabricated device.

The BOC has an overriding belief that OTS orthoses should be exempt from the competitive bidding program completely. The minimal savings that might be gained cannot offset the administrative burdens associated with the inclusion of OTS orthoses in the competitive bidding program.

The Medicare Modernization Act of 2003 (MMA), granted CMS the authority to exempt certain items from a Medicare competitive bidding program that were not likely to result in significant savings. We urge CMS to categorically exempt all OTS orthotics from the Medicare competitive bidding program on the basis that inclusion of OTS orthotics in a competitive bidding program will not produce significant savings to the Medicare program.

Actual data from the competitive bidding demonstration related to certain orthotics provides support for this position. For the 23-month period during which competitive bidding for certain orthotics was tested in San Antonio, TX, the Medicare program saved a total of $89,462, or less than $45,000 per year. CMS determined through its proposed scoring methodology that San Antonio is one of the ten largest MSAs with the highest potential for DMEPOS savings. We believe that other MSAs would likely yield even less savings than the original San Antonio demonstration. Statistics such as these lend little support to the use of competitive bidding in the provision of OTS orthotics.

Additionally, Section 1847(a)(1)(B)(ii) of the Social Security Act gives CMS the authority to phase-in competitive bidding "first among the highest cost and highest volume of items or those items that the Secretary determines have the largest savings potential." OTS orthoses are not high-cost or high-volume items nor do OTS orthoses have the largest potential for savings based on what was learned in the San Antonio demonstration.

The BOC does, however, support the use of quality standards and accreditation as a requirement for the provision of all DMEPOS. We maintain it is only through these avenues that CMS can ensure that Medicare beneficiaries receive the best possible care from highly qualified suppliers, while at the same time protect the Program by limiting unnecessary expenditures for OTS orthoses. To that end, we believe that CMS' focus should be aimed at designing, implementing and enforcing effective quality standards and mandatory accreditation requirements.

Privileging

In Dr. Fedder's letter, he expresses strong opposition to the proposed process for privileging non-credentialed or non-licensed professional staff. While we acknowledge the basis for Dr. Fedder's concerns, the BOC understands that allowing qualified, credentialed suppliers the authority to "privilege" or authorize an employee to perform certain functions is critical to ensuring cost-effective access to quality prosthetic and orthotic care. The process of privileging

entails documenting the qualifications of an individual to perform certain functions while under the supervision of an orthotist, and is an accepted documentation methodology in the majority of healthcare accreditation programs. The practice of granting privileges to healthcare paraprofessionals to allow for them to perform certain services under the supervision of a credentialed professional is a common practice in healthcare delivery, and is an avenue that the BOC supports in the provision of orthotics and prosthetics care.

Again, we appreciate this opportunity to expand upon and clarify the issues Dr. Fedder previously addressed. If we can provider any further information, please do not hesitate to contact us at (512) 965-8968 or the BOC office at the number listed above.

Respectfully Submitted,

Kay L. Zehms, BOCO, LO
Chairman of the Board
Board for Orthotist/Prosthetist Certification (BOC)